BIS VIEW™ Monitoring System
OPERATING MANUAL

Rx only

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA 02062
U.S.A.
(Tel) 617-559-7000
(Tel) 888-BIS INDE(X) (U.S. only)
(Fax) 617-559-7400
bis_info@aspectms.com
www.aspectmedical.com

EC REP
Aspect Medical Systems International B.V.
Rijnzathe 7d2
3454 PV De Meern
The Netherlands
Tel: +31.30.662.9140
Fax: +31.30.662.9150
amsint@aspectms.com

CE 0123

070-0089 1.01

BIS VIEW™ Monitoring System

OPERATING MANUAL

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ABOUT THIS MANUAL

This Operating Manual contains all of the information you need to set up and operate the Aspect™ Medical Systems' BIS VIEW™ Monitoring System (Figure 3). It also includes specific cleaning and test procedures you may occasionally be required to perform. Although this manual is intended for trained medical personnel, it does not assume prior knowledge or experience with operator-programmable medical electronics devices.

Keep this Operating Manual with the BIS VIEW monitor for use by the operator. This manual is also intended to be a service information manual for service technicians or biomedical engineering personnel.

Before attempting to set up or use the BIS VIEW system, please familiarize yourself with the safety information provided in this section.

INTRODUCING THE BIS VIEW MONITORING SYSTEM

Introduction

The BIS VIEW Monitoring System is a user-configurable patient monitoring system designed to monitor the hypnotic state of the brain based on acquisition and processing of EEG signals. The BIS VIEW system processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS, which correlates with the patient's level of hypnosis.

The BIS VIEW monitor display consists of:

- The current BIS number
- Trend graph of BIS values over time
- Raw EEG waveforms in real time
- Various signal quality indicators (EMG, SQI, SR)
- Alarm Indicator and Messages

The system performs self-tests to ensure that the monitor and its components are functioning properly and that impedance levels of patient sensors are within acceptable limits. Easy-to-use menus allow the user to change the data display and review stored data.

Important Information about Using BIS Monitoring

BIS monitoring systems are intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. They are intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

BIS is a complex monitoring technology intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. **Reliance on the BIS alone for intraoperative anesthetic management is not recommended.** As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. BIS values should also be interpreted cautiously with certain anesthetic combinations, such as those relying primarily on either ketamine or nitrous oxide/narcotics to produce unconsciousness. Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders and those taking other psychoactive medications.

The BIS education site, www.biseducation.com, offers relevant information and published articles on the clinical use of BIS. In addition, there is a "Monitoring Consciousness Using the Bispectral Index During Anesthesia" Clinician's Pocket Guide available on the website and through your local Aspect Representative.

For more information, please contact Aspect Medical Systems at (800) 442-2051. If you require additional information on the use of BIS, please contact Aspect Medical Systems Clinical Support at 800-442-8655 or 617-559-7655 if calling from outside of the USA.

SECTION 1

1 SAFETY PRECAUTIONS

INTRODUCTION

Caution:
Carefully read this entire manual before using the monitor in a clinical setting.

WARNINGS, CAUTIONS, AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A WARNING advises against certain actions or situations that could result in personal injury or death.
- A CAUTION advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.
- A NOTE provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols used on the BIS VIEW system appears at the end of this section.

1.1 Warnings

EXPLOSION HAZARD: DO NOT USE THE BIS VIEW SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

CONSIDERATIONS WHEN USING ELECTRO CONVULSIVE THERAPY (ECT) EQUIPMENT DURING BIS MONITORING:
SEPARATE ECT ELECTRODES FROM THE BIS SENSOR AS MUCH AS POSSIBLE TO MINIMIZE THE EFFECT OF INTERFERENCE.
CERTAIN ECT EQUIPMENT MAY INTERFERE WITH THE PROPER FUNCTION OF THE BIS MONITORING SYSTEM. CHECK FOR COMPATIBILITY OF EQUIPMENT DURING PATIENT SETUP.

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VIEW SYSTEM SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

DUE TO ELEVATED SURFACE TEMPERATURE, DO NOT PLACE BISx™ IN PROLONGED DIRECT CONTACT WITH PATIENT'S SKIN, AS IT MAY CAUSE DISCOMFORT.

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS DURING USE OF HIGH-FREQUENCY SURGICAL EQUIPMENT, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VIEW SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

DO NOT EXPORT BISx HISTORY DATA WHILE A CASE IS IN PROGRESS.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA), AS HAZARDOUS GASES MAY RESULT.

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE.

LEAKAGE CURRENT MUST BE CHECKED WHENEVER INSTRUMENT CASE IS OPENED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN.

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VIEW POWER SUPPLY.

1.2 Cautions

Read this entire manual carefully before using the monitor in a clinical setting.

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Do not block ventilation inlet holes on the underside of monitor.

Do not open the BISx for any reason. The seal to prevent liquids from entering the BISx may be damaged if opened.

The BIS VIEW system has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep™ technology and uses a proprietary connector. Use of other electrodes is not recommended.

Do not remove drive while export is in progress.

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the BIS VIEW monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VIEW monitor contains an internal Lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connector can interfere with PIC performance.

The BIS VIEW system complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications."

Do not disconnect the BISx during the software update.

When connecting or disconnecting BISx, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VIEW Monitoring System.

The BIS VIEW Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VIEW Monitor should be observed to verify normal operation in the configuration in which it will be used.

To completely remove power from the unit: put the monitor in standby mode, disconnect power cord from the power cord receptacle of the monitor, then remove the battery from the monitor.

The BIS VIEW monitor may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. (Refer to Section 6.4 "Using the Reset Button").

Service or repairs must be performed only by qualified biomedical technicians.

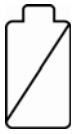
Important:
The BIS VIEW systems comply with the European Medical Device Directive (MDD) and applicable regulatory requirements of the country distributed to and carry the CE_{xxxx} Marking. Declarations of Conformity provided upon request where appropriate.

1.3 Key to Symbols

	Caution, Consult Accompanying Documents		Data I/O, RS-232 Serial Port
USB-A	Universal Serial Bus: Type A	**USB-B**	Universal Serial Bus: Type B
	Caution: Hot Surface		Storage Temperature Limits
	Type BF Equipment		Type BF Equipment Defibrillator-proof
	Alternating Current (A/C)		Direct Current (D/C)
	Battery Location		Reset Button
	Monitor Power ON		Monitor Power OFF or Standby Mode
	Do not Reuse		Use by YYYY-MM-DD or YYYY-MM
	Latex-free product		PVC-free product
	Recyclable		Crossed out wheelie bin indicates separate treatment from general waste at end of life
	Manufacturer		Date of Manufacture
EC REP	Authorized Representative in the European Community	REF	Catalog Number
LOT	Batch Code	SN	Serial Number
CE	Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CE_{XXXX} represents the Notified Body number		Classified by Underwriters Laboratories Inc.® with respect to electric shock, fire and mechanical hazards only, in accordance with UL 60601-1 and IEC60601-2-26
	Recognized under the Component Recognition Program of Underwriters Laboratories Inc.		Packaging Labeling: Fragile, Do Not Get Wet, and This Side Up

Figure 1 - Symbol Key (page 1 of 2)

Operating on Battery



No Battery is Installed in Monitor

Ringing Bell Icon – High Priority Alarm Condition exists. The alarm sounds unless the alarm key has been pressed to silence it.

Yellow Bell with dotted 'X' - Alarms Paused

Red Bell with 'X' - Alarms Silenced

Figure 1 - Symbol Key (page 2 of 2)

SECTION 2

2 SYSTEM SETUP AND PREPARATION FOR USE

INTRODUCTION

This section provides setup instructions for the Aspect BIS VIEW Monitor, BISx, and accessories. It includes:

- Setup checklist
- Proper environment
- Required equipment and supplies
- Cable connections
- Start and shutdown procedures
- Initial menu settings

2.1 BIS VIEW Monitor Setup and Checkout

1. Open packages and inspect for all components:
   - Monitor (P/N 185-0205)
   - Power cord
   - Pole clamp
   - BISx (P/N 185-0145-AMS)
   - PIC (Patient interface cable, connects BISx to patient)

   Sensors are sold separately. For a list of available sensors please contact Aspect Medical Systems, Inc. or your local distributor.

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.
   - Verify that light to right of ON/Standby button is yellow.

3. Start up monitor by pressing the ON/Standby button (lower right corner).
   - Verify that light to right of ON/Standby button is green.
   - Verify all self-tests complete successfully. (Do not connect or disconnect equipment, or press keys until the monitor has completed its tests.)
   - Verify next screen says "Connect BISx."

4. Connect BISx with PIC to monitor.
   - Verify that screen says "Connect sensor or cable."

5. Connect PIC and sensor.
   - Verify SENSOR CHECK begins.

6. Disconnect power cord from monitor.

- Verify 'OPERATING ON BATTERY BACKUP' is displayed
- Verify battery icon displays.

7. Reconnect power cord.
   - Verify battery icon is not displayed.
   - Verify "OPERATING ON BATTERY BACKUP" is not displayed.

8. End of checkout.

2.2 Environment

2.2.1 Shipping and Storage Environment

The monitor and its accessories can be stored or shipped within the following environmental limits. Note that these limits apply to non-operational storage and shipping situations.

Temperature	-10°C to +60°C
Humidity	15% to 95% (non-condensing)
Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

Protect the monitor from sudden temperature changes that can lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

2.2.2 Operating Environment

The BIS VIEW Monitoring System is not designed for use in areas containing flammable gases or vapors.

WARNING:
EXPLOSION HAZARD: DO NOT USE THE BIS VIEW SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

The BIS VIEW monitor is designed to operate safely under the following conditions. Conditions outside these ranges could affect reliability.

Temperature	0°C to +40°C
Humidity	15% to 95% (non-condensing)

Pressure	800 mm Hg (1500 feet below sea level) to 360mm Hg (20,000 feet above sea level)

2.2.3 Power Requirements and System Grounding

The BIS VIEW Monitoring System requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 0.7 ampere maximum.

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

WARNING:

USE ONLY THE POWER CORD SUPPLIED BY THE MANUFACTURER. NEVER ADAPT THE PLUG FROM THE MONITOR TO FIT A NON-STANDARD OUTLET.

U.S.A. REQUIREMENT: FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VIEW MONITOR SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

The BIS VIEW Monitoring unit **does not** contain a ***Protective Earth Stud (GND Stud)***. Since the exposed metal parts on the rear of the BIS VIEW Monitor (Communication serial port and USB ports) are separated from live parts by double insulation, a ground continuity test does not apply to these parts. The components of the BIS VIEW Monitor that are connected to protective earth are contained within its enclosure and are not accessible to the user of the equipment. However, as stated in the operating manual, an enclosure leakage current test should be performed on the exposed metal parts and should be checked periodically to ensure that the integrity of the equipment's insulation system is maintained. The leakage current test should include measurement of ground wire leakage, enclosure leakage, and patient leakage.

Ground wire leakage typically can be performed automatically by connecting the A/C power cord of the BIS VIEW Monitor into a safety tester. The enclosure leakage may be measured by any safety test equipment that is capable of connecting to isolated conductive parts and measuring the current from those parts to earth. The patient connection terminals of many safety testers can be used for this purpose. The patient leakage current can be measured by

connecting the patient connection terminals of a safety tester to the patient input connection (the PIC) of the BISx.

The BIS VIEW Monitor has been certified by Underwriters Laboratories to comply with IEC 60601-1, as indicated on the labeling on the rear of the monitor.

2.2.4 Electromagnetic Compatibility Requirements

The BIS VIEW Monitoring System should be used only with the power cord and accessories recommended and supplied by Aspect Medical Systems, Inc. The system must be set up and put into use according to the specifications described in Section8.2 "Electromagnetic Compatibility Specifications."

Caution:

The BIS VIEW system complies with the electromagnetic compatibility requirements of IEC 60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications."

2.2.5 Site Preparation: Mounting the Monitor

Aspect Medical Systems, Inc. strongly recommends permanent mounting of the BIS VIEW monitor to the anesthesia machine to enhance safety and facilitate ease-of-use. Please contact your local representative or Aspect to discuss mounting options.

WARNING:

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

2.2.5.1 Mounting the Monitor using the Pole Clamp

To mount the monitor to a secure vertical pole (1/2" - 1½" in diameter):

1. Place pole within clamp bracket and tighten screw using the black finger knob. Make sure that there is enough space above the clamp so that you have a few inches to slide the monitor in from above.
2. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp, and the monitor should snap securely into place.

Figure 2 - Pole Clamp

To remove the monitor, press tab on top of clamp shoe before sliding monitor up.

The pole clamp may be locked onto the monitor so that the two do not get separated. To do this:

1. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp and the monitor should snap securely into place.
2. Make sure that set screw hole on pole clamp aligns with corresponding hole on clamp shoe.
3. Remove black knob screw from pole clamp.
4. Using the Allen wrench supplied, secure pole clamp to monitor with the set screw provided.
5. Replace black knob screw.
6. To attach to pole, place pole within clamp bracket and tighten screw using the black finger knob.

2.2.5.2 Optional Mounting Accessories

For information on optional mounting accessories, request Aspect's "Monitor Mounting Solutions" booklet (part number 070-0031).

2.3 The BIS VIEW Monitoring System – Equipment and Supplies

The BIS VIEW Monitoring System consists of the following basic components:

- BIS VIEW Monitor (P/N 185-0205)
- BISx (P/N 185-0145-AMS)
- Patient Interface Cable (PIC)
- BIS Sensor
- Detachable Power Cord

Sensors are sold separately. For a list of available sensors please contact Aspect Medical Systems, Inc. or your local distributor.

A pole clamp is also included; however its use is optional. Contact Aspect or your local representative for information on additional equipment and accessories.

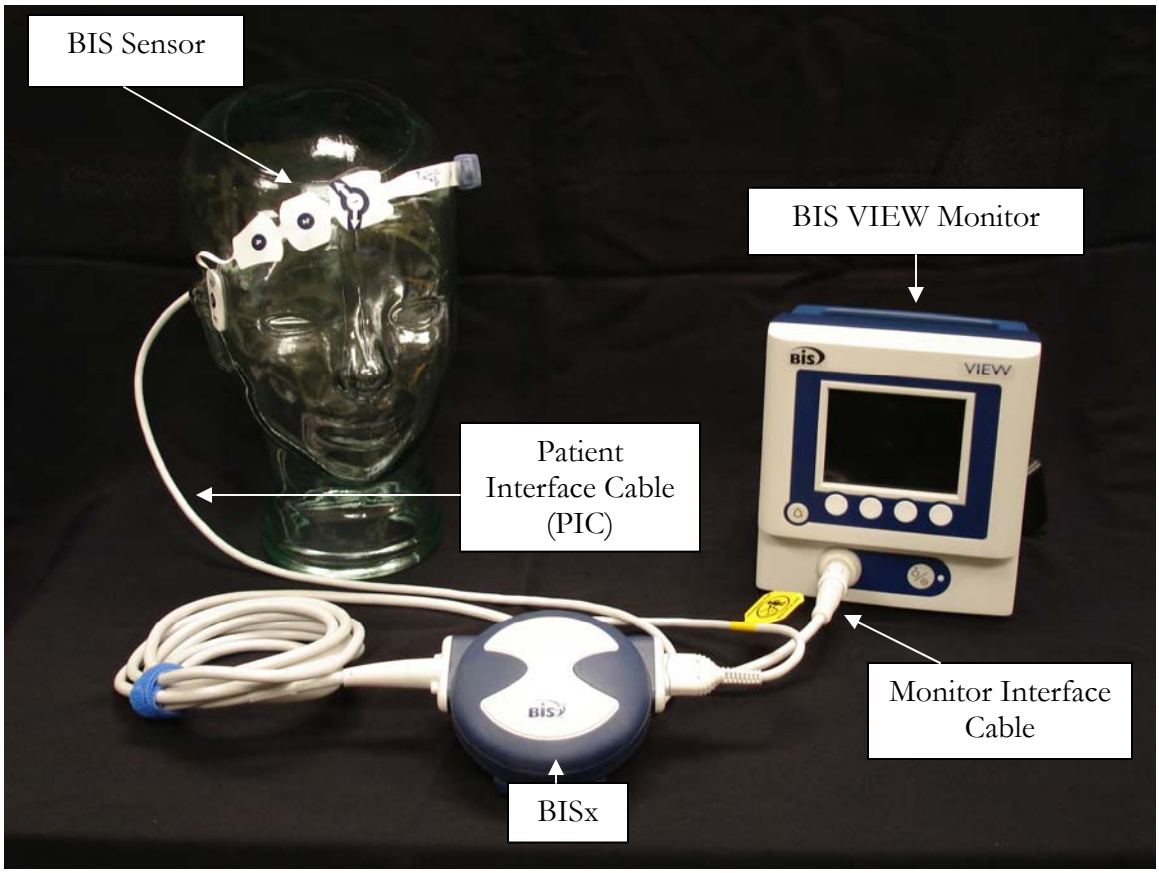


Figure 3 - The BIS VIEW Monitoring System

2.3.1 The BIS VIEW Monitor

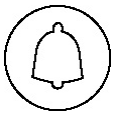
2.3.1.1 Front Panel

The front panel of the BIS VIEW monitor contains four soft keys, an alarm key, the BISx port and the ON/Standby button. See Figure 3.

2.3.1.2 Soft Keys

The four white "soft" keys directly under the BIS VIEW screen are used to make all selections. These keys are designed to function even when the user is wearing examination gloves.

2.3.1.3 Alarm Key



The Alarm Key is used to pause, silence, or reinstate audible alarms.

2.3.1.4 ON/Standby button

The ON/Standby button is located in the lower right corner of the monitor and indicates whether the monitor is ON or in Standby mode. When the small LED light to the right of the ON/Standby button is green, the unit is running and providing power to the BISx. When it is yellow, the battery is charging and the system is in Standby mode. When it is not lit, no A/C power is available to the unit; pressing the ON/Standby button will start up the monitor using the battery.

2.3.1.5 Rear Panel

The rear panel components are pictured in Figure 4. They include: two USB ports (Type A and B), the Reset button, an RS-232 port, the Battery/Power Supply cover, and the clamp shoe.

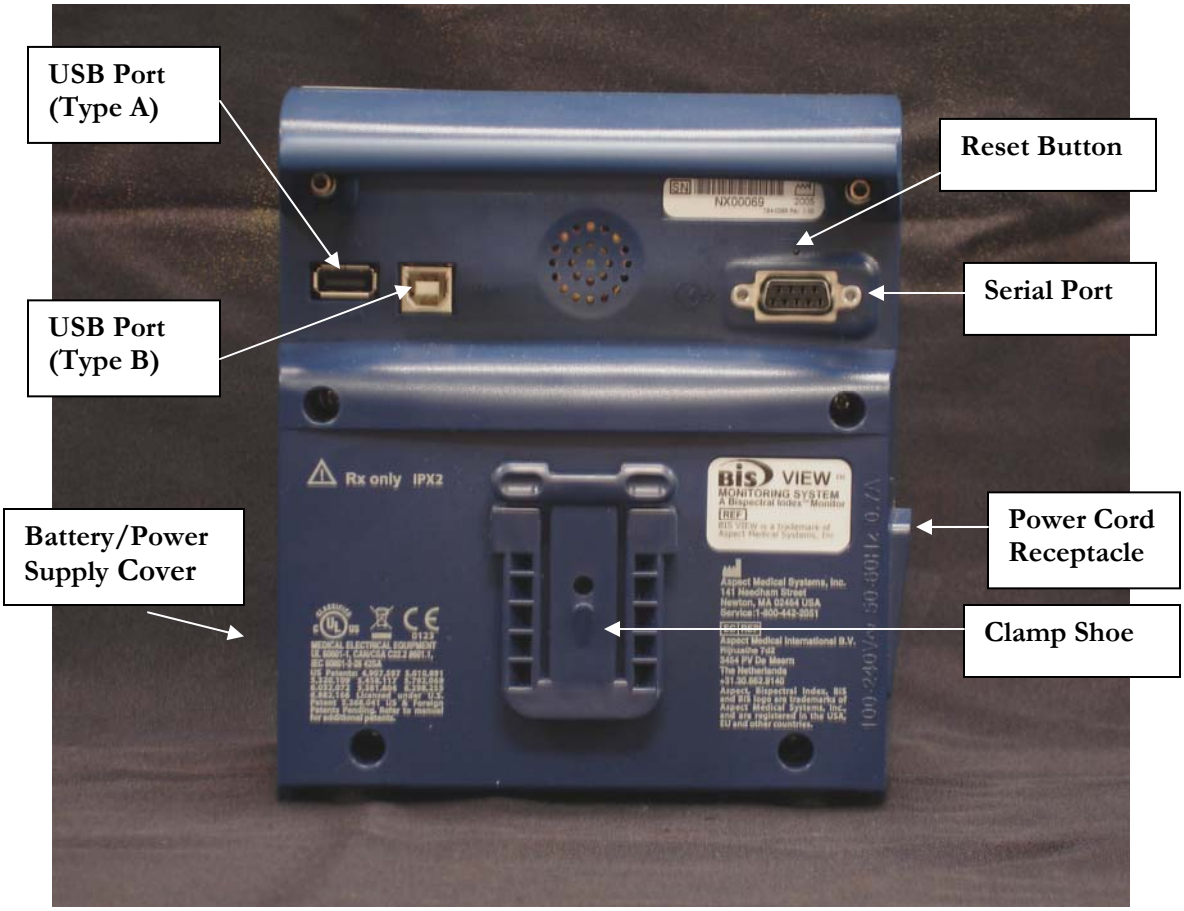


Figure 4 - Rear Panel

There are two **USB ports** on the rear of the monitor. The Type A port is used to export data to a removable drive. It is also used to update monitor and BISx software. The USB (Type B) port is for manufacturer's use only.

The **clamp shoe** allows the monitor to slide into the **pole clamp** so that it can be attached to a ½" – 1 ½" diameter vertical pole.

The **RS-232 serial port** can be used to transfer data from the monitor.

WARNING:
WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

Under normal operation, power is cycled through the ON/Standby button. The **Reset** button can be used to reset the software functions of the BIS monitor (and the BISx if it is attached) in the unlikely case that it is required. See Section 6.4 "Using the Reset Button."

The **Battery/Power Supply cover** contains the BIS VIEW monitor's power supply and allows access to its battery.

The **power cord receptacle**, located on the side of the Battery/Power Supply cover, is used to plug in the power cord provided by the manufacturer. It provides power to the monitor and to the BISx when it is attached.

Caution:
The BIS VIEW Monitoring System complies with the electromagnetic compatibility requirements of IEC60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 8.2 "Electromagnetic Compatibility Specifications."

2.3.1.6 Integral Battery

A rechargeable lithium ion battery inside the monitor provides approximately 45 minutes of back-up power when power cannot be supplied via the power cord. Recharge time is approximately 6 hours. The battery charges continually as long as the unit is plugged into A/C power.

When the system is running on battery, a battery icon displays indicating the battery status. A battery icon with four green bars indicates that the battery is fully charged. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color. In addition, a "Battery Voltage Low" message blinks in the Message area of the screen.

Caution:
Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the BIS VIEW monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VIEW monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

2.3.2 BISx

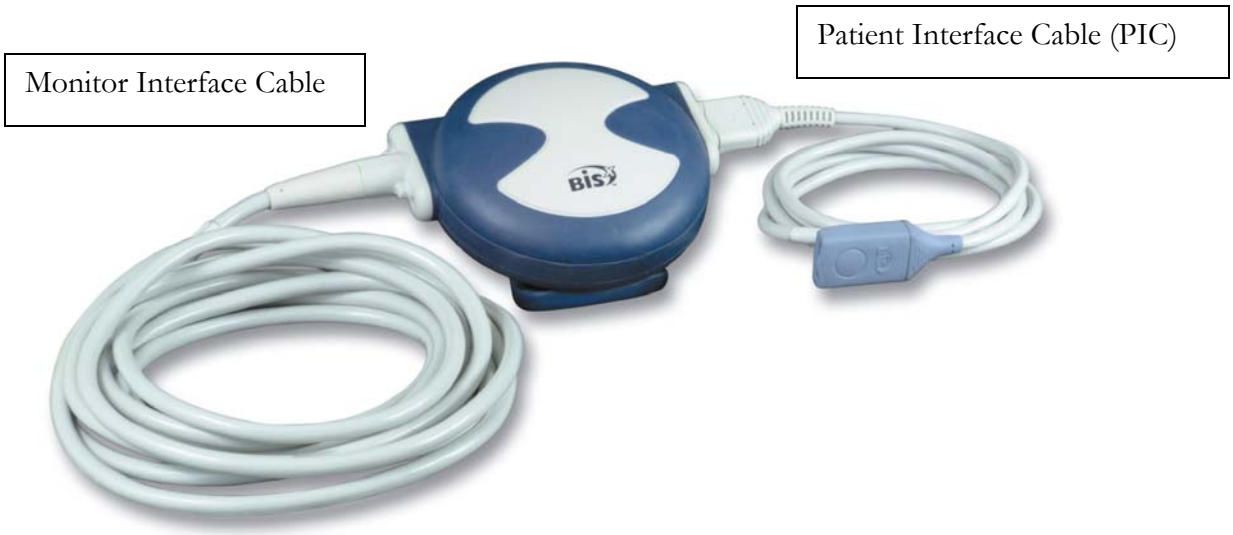


Figure 5 - BISx and PIC

The BISx receives, filters, and processes patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment.

The BISx is shown in Figure 5. Its long flexible **Monitor Interface Cable** connects to the front of the monitor. The **Patient Interface Cable (PIC)** connects the BIS sensor to the BISx.

The attachment clip on the BISx is used to secure it in a convenient location near the patient's head.

WARNING:
DUE TO ELEVATED SURFACE TEMPERATURE, DO NOT PLACE BISx™ IN PROLONGED DIRECT CONTACT WITH PATIENT'S SKIN, AS IT MAY CAUSE DISCOMFORT.

Caution:
Do not open BISx for any reason. The seal to prevent liquids from entering the BISx may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

2.3.3 Patient Interface Cable (PIC)

Aspect's BIS Sensor Patient Interface Cable (PIC) (see Figure 3) connects the BISx to the BIS sensor.

2.3.4 BIS Sensor

The sensor is the single use component of the BIS Monitoring System and should be replaced after each use. For details on how to apply the sensor to the patient and how to connect to the BIS Monitoring System, refer to the BIS Sensor's instructions for use. All sensors, including the BIS Extend Sensor, utilize the monitor's active settings (such as smoothing rate).

2.4 Cable Connections

After you have familiarized yourself with the safety information in the introductory section of this manual and have prepared a suitable environment, follow these steps to prepare the BIS VIEW system for operation.

1. **Connect the BISx to the monitor**
   Holding the cylindrical connector with the flat side up, plug the BISx Monitor Interface Cable into the BISx port on the front of the monitor.

   Once connected, the BISx need not be disconnected again. However, if you wish to disconnect the BISx cable from the monitor, carefully grasp the connector and pull. DO NOT pull on the cable.

2. **Connect the PIC to the BISx**
   Attach the gray connector of the Patient Interface Cable to the BISx.

Note:
Connect with the BIS logo facing up for proper pin alignment. To disconnect the PIC, grasp the connector housing and pull firmly. DO NOT pull apart by the cable wire.

2.5 Start Procedure

2.5.1 Starting the Monitor for the First Time

To start the instrument for the first time, after it has been reset with the RESET button, or after battery replacement:

1. Attach one end of the power cord to the receptacle on the left side of the monitor.
2. Plug the other end of the power cord into a properly grounded hospital-grade AC power outlet. A yellow light illuminates to the right of the ON/Standby button.
3. Press the ON/Standby button. The light changes to green and diagnostics tests run to verify that the system is operating properly. (Do not connect or disconnect equipment, or press keys until the monitor has completed its tests.) A beep indicates that the tests are complete. If there is a problem, the system halts and an error message appears. Error messages are explained in the Troubleshooting section of this manual.

When not in use, the monitor should be placed in Standby mode. To **put the system in Standby mode,** press and hold the ON/Standby button for two seconds before releasing. The light will change from green to yellow. If the monitor is running on battery, the light will go off completely.

Caution:

To completely remove power from the unit: put the monitor in Standby mode, disconnect power cord from the power cord receptacle of the monitor, then remove the battery from the monitor.

2.5.2 Starting the Monitor from Standby Mode

When the monitor is in Standby mode (yellow light), you may start it by pressing the ON/Standby button. The light will change to green.

When not in use, the monitor should be placed in Standby mode. To **put the system in Standby mode,** press and hold the ON/Standby button for two seconds before releasing. The light will change from green to yellow. If the monitor is not connected to A/C power, the light will go off completely.

Caution:

To completely remove power from the unit: put the monitor in Standby mode, disconnect power cord from the power cord receptacle of the monitor, then remove the battery from the monitor.

2.6 Initial Menu Settings

Before using the BIS VIEW monitor for the first time, you may need to select the proper language and set the current date and time. Other setting options are discussed in detail in Section 3.

All menu selections are made using the four soft keys located under the monitor screen. The function of each key is displayed in a box on the screen, directly above the key. To access the Menus, press the key below [MENU] on the right side of the screen. Press the keys labeled [▲] (Up) or [▼] (Down) to scroll through the menu options, and press the key under [SELECT] to make a selection. Press the key under [HOME] at any time to return to the main display screen.

From this point forward, when the user is instructed to press the [*xx*] key, it should be understood that the instruction refers to the soft key located under that label.

2.6.1 Language Selection

The BIS VIEW monitor is designed to support multiple languages. If the screen does not display the desired language, follow these steps:

To change the language:

1. Press **[MENU]** to access the Main Menu. (The MENU key is the soft key on the far right.)
2. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**. (**Maintenance** is the fourth selection on the list). Press **[SELECT]**. The Maintenance Menu appears.
3. Highlight **[Language]**. (**Language** is the third selection on the list.) Press **[SELECT]**. The Language Menu appears.
4. Use the **[-]** or **[+]** key to scroll through the available languages until the desired language displays. Press **[SELECT]**.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 2.6.3 "Save Settings."

2.6.2 Date and Time

To set the current **Date and Time**:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Date/Time]**. Press **[SELECT]**. The Date/Time Menu displays.
4. Use the [▲] or [▼] key to highlight the item that you want to change. Press **[SELECT]**.
5. Use the **[-]** and **[+]** keys to decrease or increase the item (day, month, year, hour, or minute). When the item is correct, press **[SELECT]**.
   (To exit the screen without saving changes, press **[BACK.]**)
6. When all time and date fields are correct, highlight **[Apply Change]**, then press **[SELECT]** to save the changes. The message, "Date and Time Changed" displays.

7. Press **[HOME]** to exit.

Notes:

The Date/Time is initially set for the Eastern Standard or Eastern Daylight Time zone (USA). It will be necessary for you to change the time twice per year using the Date/Time feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

When time is set to a time before the last recorded data, the following message appears on the screen: "Processing the requested change will result in loss of all data collected since *[date]*. BIS History and sensor data saved in BISx will NOT be erased." Press **[CANCEL]** to return to Date and Time Menu with no changes. Press **[CONTINUE]** to apply the requested change.

Date and time cannot be changed while a case is in progress.

2.6.3 Save Settings

The BIS VIEW monitor will always start up configured to settings that have been saved in memory. These settings appear in the "Saved Settings" list. When a user changes a setting, the change is recorded in the "Active Settings" list, but does not become a default setting until it is saved to the "Saved Settings" list.

Note:

The following settings are not saved by the Save Settings option: Impedance Checking (always returns to ON), Diagnostics Codes (returns to OFF).

To access **Settings**:

1. Press **[MENU]** to access the Main Menu.
2. Use the [▲] or [▼] key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Settings]**. Press **[SELECT]**. The Monitor Settings Screen displays the "Active" and the "Saved" settings. When the Active and Saved settings are different, they are displayed in yellow font.

To save the Active Settings to the Saved Settings list, press **[SAVE ACTIVE]**. The active settings become the new default settings for the monitor.

To return the active settings to the previously saved settings, press **[RESTORE SAVED]**. The Active Settings will now be the same as the Saved Settings.

When you have finished, press **[HOME]** to exit.

To restore original factory settings to the monitor, go to MENU>Maintenance>Default Settings and press **[RESTORE]**. See Section 6.1.2, "Default Settings" for details.

SECTION 3

3 OPERATING THE BIS VIEW MONITORING SYSTEM

INTRODUCTION

This section covers:

- Preparing for operation
- The sensor check
- The three monitor screen displays: BIS Number Display Screen, BIS Trend Display Screen with Sensor Status and BIS Trend Display Screen with EEG Waveforms
- Software menus and menu selections
- Ending a case

Read this section before operating the monitor in a clinical setting.

3.1 Preparing for Operation

After you have familiarized yourself with the safety information in the introductory section of this manual, prepared a suitable environment, properly connected the BISx and PIC cables, and completed the initial settings described in Section 2, follow these steps to prepare the BIS VIEW Monitoring System for operation.

1. Startup and System Check
Press the ON/Standby button on the lower right corner of the monitor to start the monitor. The light changes from yellow to green, and the system initiates a self-test to make sure that all equipment is operating properly.

2. Attach BIS Sensor to Patient
Prepare sensor site and place the BIS sensor on the patient in accordance with the instructions included on the sensor packaging.

Caution:
The BIS VIEW Monitoring System has been designed to operate with a BIS sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep technology and uses a proprietary connector. Use of other electrodes is not recommended.

WARNINGS:

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS DURING USE OF HIGH-FREQUENCY SURGICAL EQUIPMENT, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VIEW SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

3. Secure the BISx

Using the attachment clip, secure the BISx to a convenient location near the patient's head.

4. Attach the BIS Sensor to the PIC

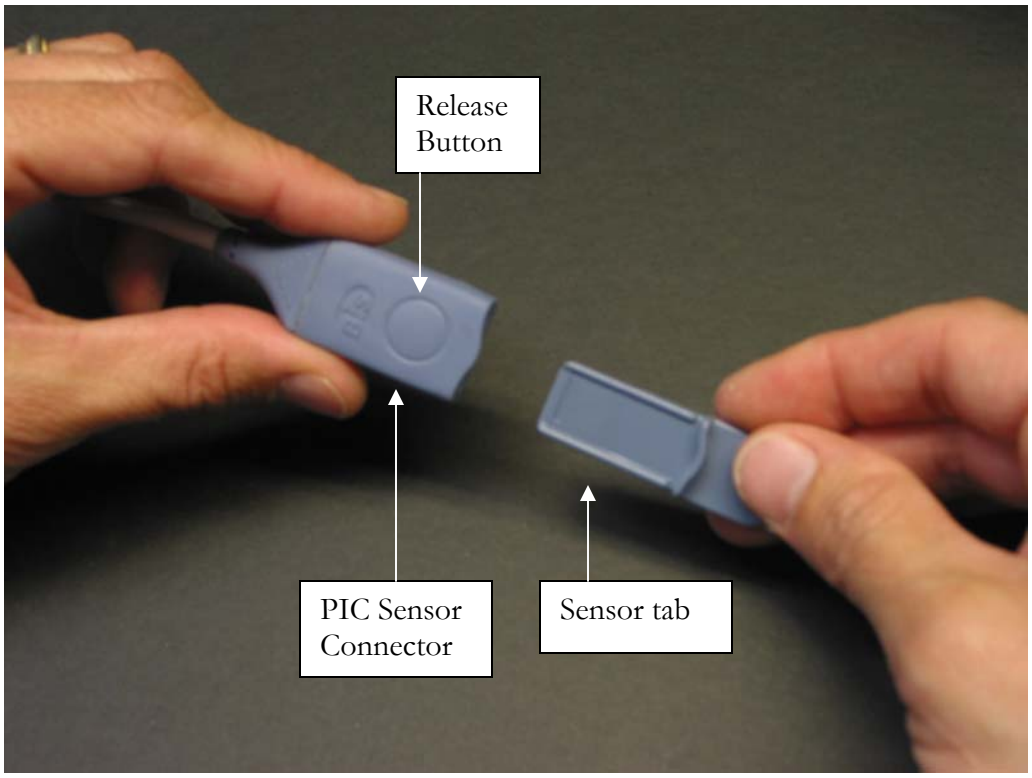


Figure 6 - Connecting the PIC

To insert the sensor into the PIC, line up as shown and insert the sensor tab into the PIC sensor connector until an audible "click" is heard. The blank side of the sensor tab (i.e. the side without the computer chip) should be facing up.

The Sensor Integrity Check is initiated each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

3.2 Sensor Check

The Sensor Check tests the impedance of each electrode on the BIS sensor to verify that it is within an acceptable range for monitoring. A Sensor Check is initiated automatically when the sensor and PIC are connected to the BISx. It may also be initiated by the user by pressing the **[SENSOR CHECK]** soft key.

The message, "Sensor Check in Progress" appears. When the sensor successfully passes the test, the Main Screen displays and monitoring begins.

If the sensor does not immediately pass the test, or if the user has manually initiated the test, the Sensor Check Graphic Screen displays. This screen shows a sensor with a symbol inside each electrode. The symbol indicates the status of that electrode:

- A circle with a question mark indicates that no status is available (Lead is off).
- A green circle with a checkmark indicates that the electrode impedance is within the acceptable range. If all electrodes contain a checkmark, monitoring can begin.
- A red circle with an 'X' indicates that the electrode impedance is not within the acceptable range.

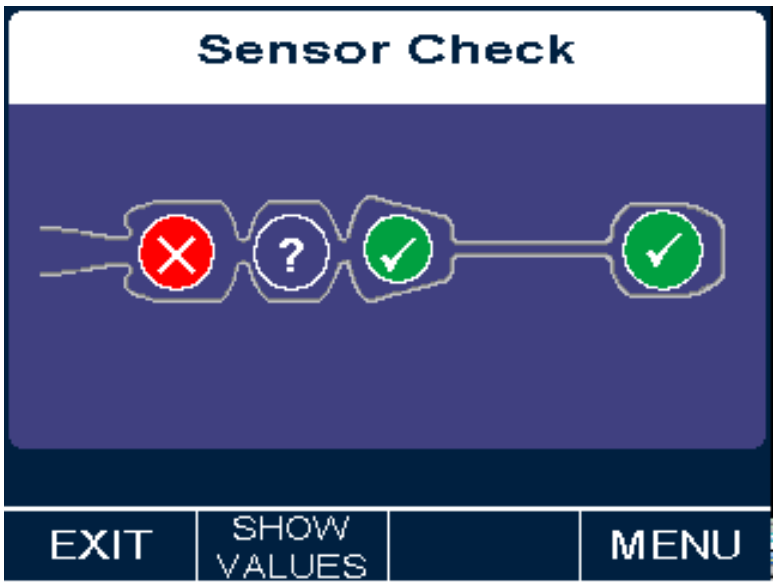


Figure 7 - Sensor Check Graphic Screen

The monitor continues updating the values until all impedance values are acceptable. To end the impedance test, press **[EXIT]**. The Sensor Check impedance test must be successfully completed before normal processing resumes.

The "Show Values" Sensor Check Display:
Additional detail may be viewed on this screen by pressing the **[SHOW VALUES]** soft key. In this display, the impedance value for each electrode, in kilo ohms, appears on the screen along with its status:

PASS - An electrode passes if the impedance for that electrode is less than 7.5 kilo ohms. The ground electrode (element #2) must be less than 30 kilo ohms to pass.

HIGH - An electrode is labeled "HIGH" if its impedance value is above 7.5 kilo ohms. As long as the combined impedance of electrodes #1 and #3 and the combined impedance of electrodes #1 and #4 are less than 15 kilo ohms, the sensor check will be considered successful.

NOISE - If the signal from the electrode goes beyond the measurable range, the label "NOISE" displays.

LEAD OFF - If the impedance check indicates that the electrode is not in contact with the patient, the label "LEAD OFF" displays.

If an electrode does not pass the impedance check, press the edges of the sensor to ensure adhesion and then press each circle for 5 seconds to ensure proper contact. If the problem persists, re-prep the electrodes and check all connections. The monitor will continue to check impedance until it is acceptable.

The "Show Values" Sensor Check Display may be selected as the default Sensor Check screen display if desired. See Section 3.6.3.1 "Screen Options" for details.

3.3 BIS Number Display Screen

The BIS Number Display Screen is the default screen display. Once the sensor check has successfully completed, monitoring begins and the BIS Number Display Screen appears. This screen displays the following information:

- The BIS value
- The battery icon (if the system is running on battery power)
- An alarm icon (when the alarms are sounding or have been paused or silenced)
- Signal quality indicator
- EMG indicator
- A unique case ID number
- System messages

To set a different screen as the default screen, see Section 3.6.3.1 "Screen Options"

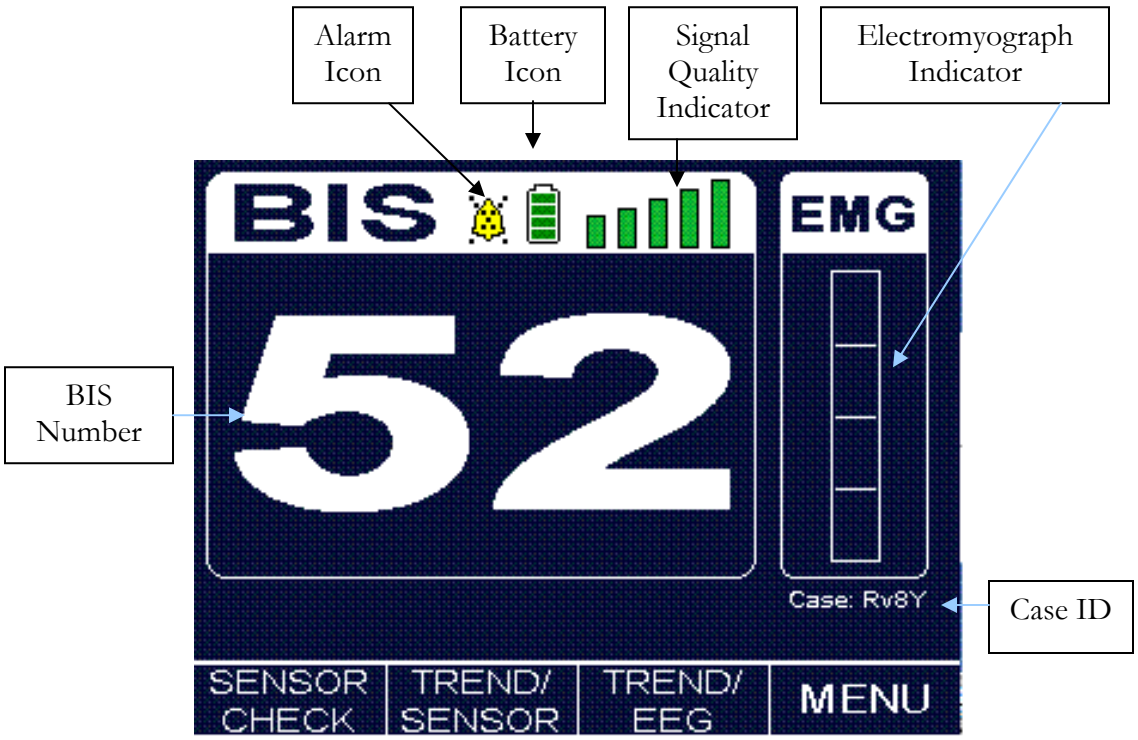


Figure 8 - BIS Number Display

3.3.1 BIS (Bispectral Index) Value

The current numeric value of the BIS is displayed in the upper left corner of the screen. The BIS number is displayed and continuously updated during all display modes as long as signal quality is sufficient.

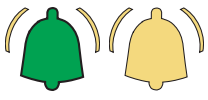
3.3.2 Battery Icon

The battery icon is displayed in the title bar above the BIS number or in the top right corner of the screen when the monitor and BISx are running on battery power. When the battery icon is filled with green bars, the battery is fully charged. When the icon turns orange, the battery is nearly depleted.

If an empty battery icon displays on the screen with a slash across it, there is no battery in the monitor.

3.3.3 Alarm Icon

The alarm icon indicates the status of the alarms. It is displayed in the title bar above the BIS number or in the top right corner of the screen when an alarm is sounding or when the alarms have been paused or silenced. The user may press the alarm key on the front of the monitor to change the alarm status:

(No Bell Icon Displayed) Alarms Active	When no bell icon is displayed, all alarms are active. Pressing the alarm key pauses all alarms for two minutes.
 Alarms Paused	A yellow bell with a dotted 'X' over it indicates that all alarms have been silenced for two minutes. When this icon is displayed, pressing the alarm key changes the alarm status to "Alarms Silenced" and the red bell icon displays.
 Alarms Silenced	The red bell with a solid "X" over it indicates that all alarms have been silenced indefinitely. When this icon is displayed, pressing the alarm key restores the active alarms.
 Alarm Sounding	When a high priority alarm is sounding, the ringing bell displays, alternating between yellow and green. Pressing the alarm key silences the current alarm, but does not prevent other alarms from sounding if another alarm condition should occur. The alarm sounding icon continues to display as long as the alarm condition exists.

3.3.4 Signal Quality Indicator

The Signal Quality Indicator (SQI) is a measure of the signal quality for the EEG channel source and is calculated based on impedance data, artifact, and other variables. The SQI bar graph is displayed in the title bar above the BIS number. Signal quality is optimal when all five bars are green. When signal quality is too low to accurately calculate a BIS value, the BIS value and other trend variables that are adversely affected by artifact will not be displayed on the screen.

3.3.5 Electromyograph (EMG) Indicator

The EMG bar graph displays the power (in decibels) in the frequency range 70 - 110 Hz. This frequency range contains power from muscle activity (i.e., electromyography or "EMG") as well as power from other high-frequency artifacts. When the indicator is low, it indicates that EMG activity is low. **BIS monitoring is optimal when the bar is empty.**

1 bar represents power in the 30-38 range
2 bars represent power in the 39-47 range
3 bars represent power in the 48-55 range
4 bars represent power greater than 55.

An EMG trend line can be added to the BIS Trend Display screens. See Section 3.6.3.1 "Screen Options."

3.3.6 Case ID

A new case number is assigned each time a new sensor is attached and passes the Sensor Check. Case ID is displayed on the BIS Number Display Screen and the Chart Data screen.

3.3.7 Message Region

The Message Region is a space reserved for status and error messages, just below the BIS Number. Messages are prioritized so that a high priority message displays before a lower priority message. The background color of the message indicates its priority:

Message Priority	Background Color
High	Orange
Medium	Yellow
Low	Light Blue
Information only	Dark Blue

Diagnostic codes may be displayed above the messages by activating them in the Diagnostic Menu. Specific error messages are explained in the Troubleshooting section of this manual (Section 6).

3.3.8 Soft Key Screen Selections

From the BIS Number screen, the user may use the four soft keys to:

- Initiate a Sensor Check
- Change the screen display to the BIS Trend Display Screen with Sensor Status
- Change the screen display to the BIS Trend Display Screen with EEG, or
- Access the Menu system.

3.4 BIS Trend Display Screen with Sensor Status

The BIS Trend Display Screen can be displayed by pressing the **[TREND/SENSOR]** soft key at the bottom of the screen. The following information displays:

- The BIS Number display in a smaller format
- Current Sensor Status - A diagram of the sensor shows the PASS/FAIL status of each electrode
- A graph of the BIS numbers plotted over a one hour time period

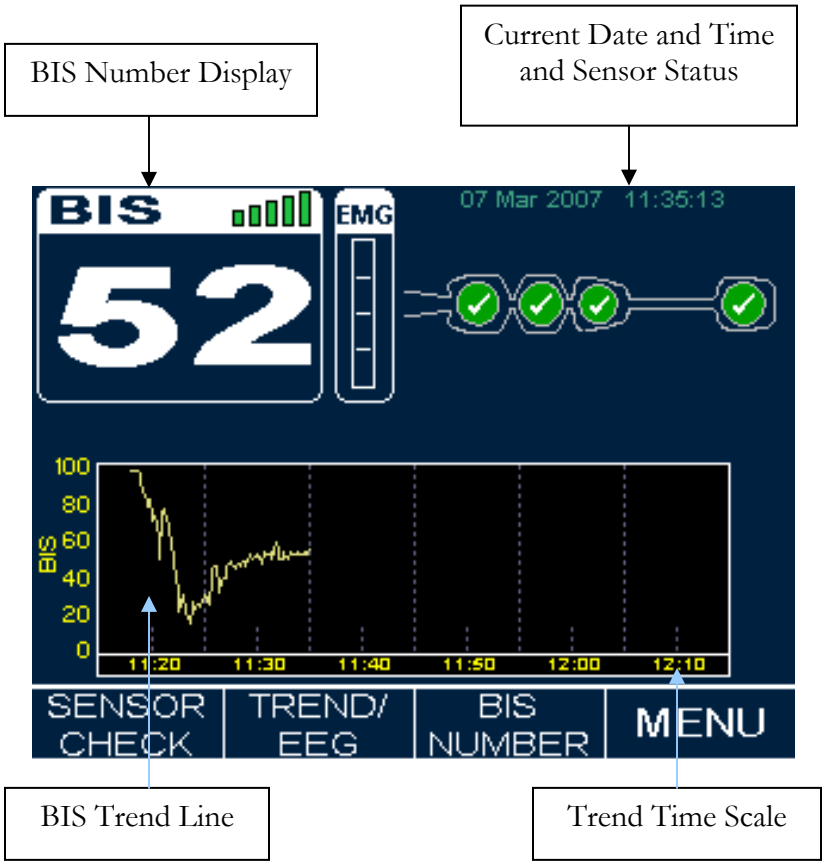


Figure 9 - Screen Features – BIS Trend Display Screen with Sensor Status

To make this screen the default screen, go to: MENU>Setup>Screen Options>BIS Display and select **Trend/Sensor Status**. See instructions in Section 3.6.3.1 "Screen Options."

3.4.1 BIS Trend Graph

The BIS Trend Graph plots the values of the Bispectral Index over a 1 hour time period. The **BIS trend** is indicated with a thick line and its unit labels appear on the left axis. The current date and time display in the top right section of the screen (See Figure 9 and Figure 10). A secondary trend line showing EMG activity may be added to the graph, if desired, by requesting it in the Screen Options Menu.

3.4.2 Target Range

A target range of optimal BIS values may be set by the user. When activated, this target range displays on the BIS Trend Graph.

If a **target range** for BIS has been set, the target area displays as two horizontal lines showing the upper and lower target ranges. If the BIS value falls outside of the target range, a message displays in the Message Region of the screen, and if an audible alarm was requested in the target range setup screen, the alarm sounds (unless alarms have been silenced). The alarm continues to sound until the BIS value returns to the target range or the alarm is silenced by pressing the alarm key. See Section 3.6.3.2 "Alarms: The Alarms Menu" for more information.

3.5 BIS Trend Display Screen with EEG

The BIS Trend Display Screen with EEG can be displayed by pressing the **[TREND/EEG]** soft key at the bottom of the screen. The following information displays:

- The BIS Number display in a smaller format
- The BIS Trend Graph (See Section 3.4.1 "BIS Trend Graph")
- EEG waveforms
- Suppression Ratio (SR), if requested in the Screen Options Menu. See Section 3.6.3.1 "Screen Options" for details.

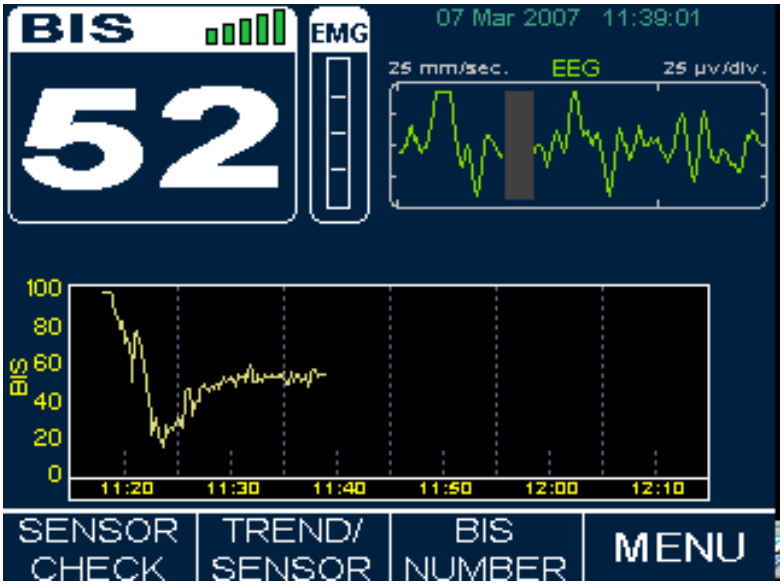


Figure 10 - BIS Trend Display Screen with EEG

Filtered electroencephalogram (EEG) waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division. When artifact is present, the label 'artifact' is displayed at the top of the screen. When the artifact is excessive, a message appears in the message region of the screen, and data that could be corrupted by artifact, such as the BIS number, are not displayed.

A test is performed immediately after every sensor check and at 10-minute intervals during monitoring to check the status of the patient ground connection. During the test, the EEG display shows a flat line and the message "GROUND CHECK" displays on the screen.

To make this screen the default screen, go to: MENU>Setup>Screen Options>BIS Display and select **Trend/EEG** See instructions in Section 3.6.3.1 "Screen Options."

3.6 Menu Selections

Before using the BIS VIEW monitor for the first time, you may want to update the monitor with your desired screen settings and the current date and time. You should also familiarize yourself with the various menu options available. This section describes the menu options available and how they work.

To make a selection from a menu, use the [▲] (Up) or [▼] (Down) soft keys until the desired menu item is highlighted, then press [SELECT] to make your selection. To exit without making a selection or changing a setting, press [HOME].

Main Menu:

Press **[MENU]** to access the Main Menu.
The Main Menu options are:

- Chart Data
- Export Data
- Setup
- Maintenance
- Diagnostics
- Demo Case

3.6.1 Chart Data

When selected, this option provides a listing of BIS, SQI, EMG and SR values at a selected time interval, so that they can be recorded on the patient chart. The Case ID number and case start and end times are displayed at the top of the screen. When the start time is yellow, the beginning of the case is displayed on the screen. When the case end time is yellow, the end of the case is displayed on the screen. When start or end time is grey, more data for that case can be viewed by pressing the **[▲]** or **[▼]** key.

The charting interval can be changed by the user on the screen and the default interval can be set in the menu system. Available intervals are 1, 5, 10 and 15 minutes. When signal quality is less than half of the level desirable for optimal monitoring conditions, an asterisk (*) displays next to the SQI number. When signal quality is too low to accurately calculate a

BIS value, no BIS number displays. Note that SR will only appear if the "Display SR" option was selected in the "Screen Options" menu.

To access **Chart Data:**

1. Press **[MENU]** to access the Main Menu.
2. Highlight **[Chart Data]**. Press **[SELECT]**. The Chart Data displays.
3. Use the **[▲]** and **[▼]** keys to scroll through the data.

To change the Charting Interval, press **[INTERVAL]** to scroll through the available options (1, 5, 10 or 15 minutes).

To permanently save the charting interval, go to MENU>Setup>Screen Options>Charting Interval, to select the desired interval, then save using the "Save Settings" option. See instructions in Section 3.6.3.1 "Screen Options."

3.6.2 Export Data

This selection allows the user to send data to a removable drive via the USB port (Type A) at the rear of the monitor, or to a device connected to the monitor's serial port. Recommended USB drives include:

- Sandisk Cruzer Mini and Micro 128, 256, 512 MB or 1 G
- PNY Attache 256 or 512 MB
- Memorex TravelDrive 512 MB
- Kingston DataTraveler 512 MB
- Aspect 32 MB and Aspect 128 MB

Data that may be exported include:

- **Live Data:** When this option is selected, live case data (BIS values, SQI, EMG, SR and unfiltered EEG waveforms) are exported.
- **BISx History Data:** When this option is selected, case data stored in the BISx (BIS values, SQI, EMG and SR) are exported.
- **Monitor Error Log:** This option reports all system errors, including those related to the monitor, BISx, PIC or sensor.

Information on the data file format may be obtained by contacting Technical Service. (See back cover for contact information.)

WARNING:
DO NOT EXPORT BISx HISTORY DATA WHILE A CASE IS IN PROGRESS.

Before exporting BISx history data:

1. Disconnect the BISx.
2. Disconnect sensor from PIC.
3. Reconnect the BISx only.

If a case is in progress during Live Data or Monitor Error Log exports, the BIS number will continue to update and display.

In order to export data, the system must be powered ON and the BISx must be connected to the monitor. If the removable drive has a "write protect" switch, it must be set to the "unlock" position. Plug the removable drive into the USB-A port on the back of the monitor. To access the **Export Data** function:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Export Data]**. Press **[SELECT]**.
3. Highlight **[Source]**. Press **[SELECT]**.
4. Highlight the data source you want to export (Live Data, BISx History, or Monitor Error Log), then press **[SELECT]**. The Export Data Menu re-displays.
5. Highlight **[Begin Export]**. Press **[SELECT]**. The message "In Progress" displays.
6. When the export status screen displays "100% complete," the drive may be removed from the back of the monitor. To stop Live Export, press **[STOP]** before removing the drive.

To exit while the export is still running, press **[HOME]**. To stop the export, press **[STOP]**.

Caution:
Do not remove drive while export is in progress.

3.6.3 Setup

The Setup Menu contains these options:

- Screen Options
- Alarms (set target range, set and test alarm volume)
- Smoothing Rate (set smoothing rate to 10, 15, or 30 seconds)
- Date and Time
- Settings (view or save settings)

3.6.3.1 Screen Options

The Screen Options Menu includes the following:

- **BIS Display:** The BIS VIEW may be set so that the most frequently used screen display becomes the default screens. There are three screen choices:
  - The BIS Number Display Screen,
  - The BIS Trend Display Screen with Sensor Status
  - The BIS Trend Display Screen with EEG.
- **Sensor Check Values:** Simple pass/fail status, or detailed impedance information may be displayed.
- **Charting Interval** (Chart Data Screen): Charting interval may be set to display at various intervals.
- **Display SR** (Suppression Ratio): The Suppression Ratio can be displayed on the BIS Trend Display Screen with EEG and the Chart Data Screen. Suppression Ratio (SR) is a calculated parameter to give the user an indication when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state, for example: SR=11 (isoelectric over 11% of the last 63 second review). The SR is displayed in the

upper right corner of the screen. When SR reaches 100%, the message "Isoelectric EEG detected" will notify the user.

- **Secondary Variable:** EMG can be plotted as a secondary variable on the BIS Trend graph.

To access **Screen Options**:

1. Press **[MENU]** to access the Main Menu.
2. Use the [▲] or [▼] key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Screen Options]**. Press **[SELECT]**. The screen options display, followed by their current default settings.
4. Highlight the screen option that you would like to change, then press **[SELECT]**. A new screen displays, listing the available options.
5. Highlight the desired option, then press **[SELECT]**.
6. Press **[BACK]** to go back to the previous screen.

3.6.3.2 Alarms: The Alarms Menu

Alarms sound to alert the user to possible problems with the patient or the equipment. Alarm conditions are prioritized so that high priority alarms take precedence over lower priority alarms. The user may silence the currently sounding alarm or silence all alarms, and may also set the alarm volume. (See Section 3.3.3 "Alarm Icon" for additional information.)

The Alarms Menu allows users to:

- Set the target range of BIS values
- Set and test the alarm volume

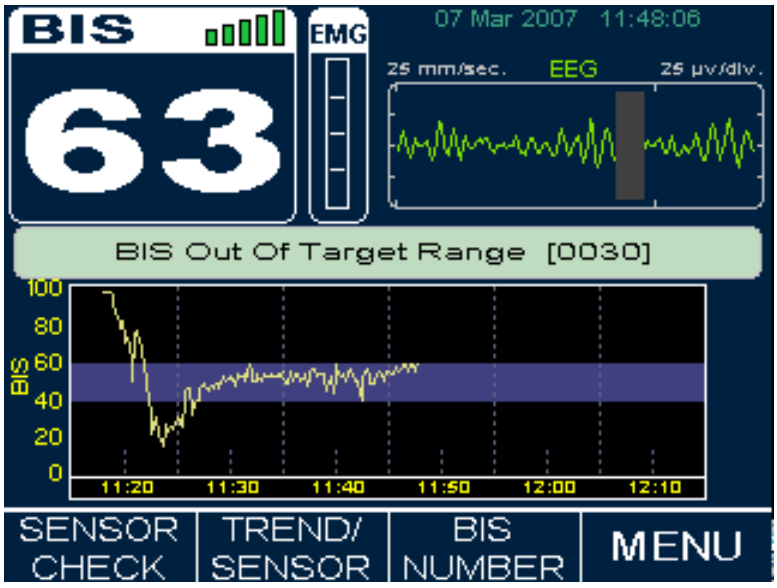


Figure 11 - Trend Display with Target Range

3.6.3.2.1 Target Range

To aid in patient management, a target range of desired BIS values may be set. When the Target Range is activated, the selected range displays on the BIS Trend Graph. When the Target Alarm is ON, an alarm notifies the user whenever the patient's BIS value falls outside of the intended range.

To access the Target Range:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**.
3. Highlight **[Alarms]**. Press **[SELECT]**.
4. Highlight **[Target Range]**. Press **[SELECT]**.

Target Range: BIS High Limit:

To set the High Limit for the BIS value,

1. Use the **[▲]** or **[▼]** key to highlight **[BIS High Limit]**. Press **[SELECT]**.
2. Press the **[+]** key to raise the upper limit by 5, or press the **[-]** key to lower the upper limit by 5. A high value of 100 = none.
3. When the desired number is displayed, press **[SELECT]**. To leave the High Limit unchanged, press **[HOME]**.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings."

Target Range: Low Limit:

To set the Low Limit for the BIS value:

1. Use the **[▲]** or **[▼]** key to highlight **[BIS Low Limit]**. Press **[SELECT]**.
2. Press the **[+]** key to raise the lower limit by 5, or press the **[-]** key to decrease the lower limit by 5. A low limit of 0 = none.
3. When the desired number is displayed, press **[SELECT]**. To leave the Low Limit unchanged, press **[HOME]**.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings."

Target Range Active: Yes/No

To activate the Target Range so that it displays on the BIS Trend Graph, or deactivate it so that it does not:

1. Use the **[▲]** or **[▼]** key to highlight **[Target Range Active]**. Press **[SELECT]**.
2. Use the **[▲]** and **[▼]** keys to select 'Yes' (active alarms) or 'No' (alarms not active).
3. When the desired selection is highlighted, press **[SELECT]**.
4. Press **[BACK]** to exit.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings: Active and Saved Monitor Settings."

Target Alarm: On/Off

To activate the target alarms so that they sound when the patient's BIS value falls outside of the desired range, or to deactivate the alarms so that they do not:

1. Use the **[▲]** or **[▼]** key to highlight **[Target Alarm]**. Press **[SELECT]**.
2. Use the **[▲]** and **[▼]** keys to select 'On' or 'Off'.
3. When the desired selection is highlighted, press **[SELECT]**.
4. Press **[BACK]** to exit.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings."

3.6.3.2.2 Alarm Volume Menu / Test Alarm Volume

The alarms can be set to sound at LOW, MEDIUM, or HIGH volume. A **Test Alarm Volume** option is provided to listen to the volume that has been set.

To access the Alarm Volume Menu and set the alarm volume:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Alarms]**. Press **[SELECT]**. The Alarms Menu displays.
4. Highlight **[Alarm Volume]**. Press **[SELECT]**. The Alarm Volume Menu appears.
5. Highlight the desired volume (High, Medium, or Low). Press **[SELECT]**.
6. Press **[BACK]** to return to the previous screen. To test the alarm volume, highlight **[Test Alarm Volume]** and press **[SELECT]**.
7. Press **[BACK]** to exit.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings."

3.6.3.3 Smoothing Rate: The Smoothing Rate Menu

The BIS VIEW system offers three choices of smoothing rates over which the BIS value is averaged:

- 10 seconds: Provides increased responsiveness to state changes, such as induction or awakening.
- 15 seconds: This is the default setting.
- 30 seconds: Provides a smoother trend with decreased variability and sensitivity to artifact.

To access the **BIS Smoothing Rate**:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Smoothing Rate]**. Press **[SELECT]**. The Smoothing Rate Menu displays.
4. Highlight the desired BIS smoothing rate. Press **[SELECT]**.
5. Press **[HOME]** to exit.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 3.6.3.5 "Settings: Active and Saved Monitor Settings."

3.6.3.4 Date/Time

The date and time may be changed at any time as long as a case is not in progress. To set the current **Date and Time**:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.
3. Highlight **[Date/Time]**. Press **[SELECT]**. The Date/Time Menu displays.
4. Use the [▲] or [▼] key to highlight the item that you want to change. Press **[SELECT]**.
5. Use the **[-]** and **[+]** keys to decrease or increase the item (day, month, year, hour, or minute). When the item is correct, press **[SELECT]**.
   (To exit the screen without saving changes, press **[BACK].**)
6. When all time and date fields are correct, highlight **[Apply Change]**, then press **[SELECT]** to save the changes. The message, "Date and Time Changed" displays.
7. Press **[HOME]** to exit.

Notes:

The Date/Time is initially set for the Eastern Standard or Eastern Daylight Time zone (USA). It will be necessary for you to change the time twice per year using the Date/Time feature if you are located in a time zone that alters its clocks at the beginning or end of Daylight Savings Time.

When time is set to a time before the last recorded data, the following message appears on the screen: "Processing the requested change will result in loss of all data collected since *[date]*. BIS History and sensor data saved in BISx will NOT be erased." Press **[CANCEL]** to return to Date and Time Menu with no changes. Press **[CONTINUE]** to apply the requested change.

Date and time cannot be changed while a case is in progress.

3.6.3.5 Settings: Active and Saved Monitor Settings

The BIS VIEW monitor will always start up configured to settings that have been saved in memory. These settings appear in the "Saved Settings" list. When a user changes a setting in the menu system, the change is recorded in the "Active Settings" list, but does not become a default setting unless it is saved to the "Saved Settings" list.

Note:

The following settings are not saved by the Save Settings option: Impedance Checking (always returns to ON), Diagnostics Codes (returns to OFF).

To access **Settings**:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Setup]**. Press **[SELECT]**. The Setup Menu displays.

3. Highlight **[Settings]**. Press **[SELECT]**. The Monitor Settings Screen displays the "Active" and the "Saved" settings. When the Active and Saved settings are different, they are displayed in yellow font.

To save the **Active** settings to the Saved Settings list, press **[SAVE ACTIVE]**. The active settings become the new default settings for the monitor.

To return the active settings to the previously **Saved** settings, press **[RESTORE SAVED]**. The Active Settings will now be the same as the Saved Settings.

When you have finished, press **[HOME]** to exit.

To restore original factory settings to the monitor, go to MENU>Maintenance>Default Settings and press **[RESTORE]**. See Section 6.1.2, "Default Settings" for details.

3.6.4 Maintenance

The Maintenance Menu includes maintenance functions to update the monitor and BISx software, view and restore default monitor settings, and change the language.

To display the Maintenance Menu:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**. Press **[SELECT]**. The Maintenance Menu appears.

Use of the Maintenance Menu is covered in Section 6, "Diagnostics and Troubleshooting."

3.6.5 Diagnostics

Contact Aspect Medical Systems, Inc. for instructions on use of the Diagnostic Menu. See the back cover of this manual for contact information.

To display the Diagnostic Menu:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Diagnostics]**. Press **[SELECT]**. The Diagnostics Menu appears.

3.6.6 Demo Case

A demonstration case is available for use in familiarizing users with the BIS monitoring system. This option allows the user to run or stop a demonstration case. When the Demo Case is selected, the Main Screen appears, with the heading, "Demo Case."

Note: The Demo Case function uses pre-stored simulated case data. It should not be used during patient monitoring at any time.

To access **Demo Case:**

1. Press **[MENU]** to access the Main Menu.

2. Use the **[▲]** or **[▼]** key to highlight **[Demo Case]**. Press **[SELECT]**. The message, "Press START to begin Demo Case" displays. If the BISx is connected, the system assumes that a case may be in progress and issues a warning.
3. Press **[START]** to start the Demo Case, or **[HOME]** to cancel.

To stop the **Demo Case**:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Demo Case]**. Press **[SELECT]**. The messages, "In progress" and "Press STOP to end the Demo Case. Press CONTINUE to continue the Demo Case" display.
3. Press **[STOP]** to stop the Demo Case, or **[CONTINUE]** to continue.

3.7 Ending a Case

When the case has finished:

- Disconnect the patient sensor from the PIC:
  - Press the release button on the connector and pull the connectors apart.
  - DO NOT pull apart by the cable wires.
- Remove BIS sensor from patient. Disposable sensors are single-use only.
- Be sure to leave the PIC with the monitor so that it is not inadvertently discarded.
- If this is the last procedure of the day, press and hold the ON/Standby button for two seconds before releasing to put the BIS VIEW monitor in Standby mode (a yellow light displays)
- Clean the BIS VIEW system between uses. See Section 5.1.

WARNING:
SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

Note: The BIS VIEW can remain plugged in to A/C power at all times.

3.8 Data Transfer

Three ports on the rear of the BIS VIEW monitor facilitate data transfer. The USB (Type A) port is used to export data to a removable drive and to update monitor and BISx software. See the following sections for use of the USB-A port:

- 3.6.2 "Export Data"
- 6.1.1 "Software Update"

An RS-232 port is available to connect the monitor to a patient monitoring system using an ASCII serial port protocol.

The USB (Type B) port is for manufacturer's use only.

WARNINGS:

THE USE OF ACCESSORY EQUIPMENT NOT COMPLYING WITH THE EQUIVALENT SAFETY REQUIREMENTS OF THIS EQUIPMENT MAY LEAD TO A REDUCED LEVEL OF SAFETY OF THE RESULTING SYSTEM. CONSIDERATION RELATING TO THE CHOICE SHALL INCLUDE:

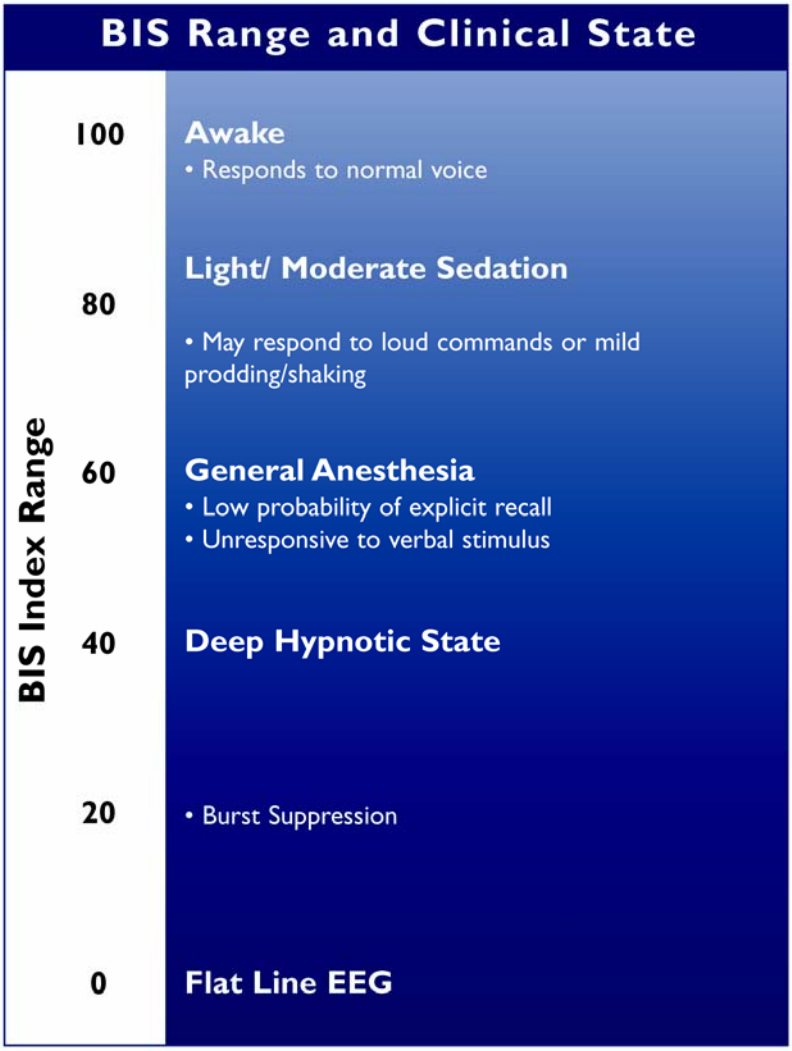
- **USE OF THE ACCESSORY IN THE PATIENT VICINITY**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-1-1 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1-1 LIMIT.

3.9 How the BIS VIEW Monitoring System Works

A sensor placed on the patient's head transmits EEG signals to the BISx. The BISx filters the data, analyzes it for artifact and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

BIS Range Guidelines are illustrated in Figure 12. A list of the processed variables and a description of each is provided in Appendix I. These data are displayed on the screen according to the preferences set by the user in the menu system. Individual screen features are covered in Sections 3.1 through 3.6



This chart reflects a general association between clinical state and BIS values. Ranges are based on results from a multi-center study of the BIS involving the administration of specific anesthetic agents. BIS values and ranges assume that the EEG is free of artifacts that can affect its performance. Titration of anesthetics to BIS range should be dependent upon the individual goals established for each patient. These goals and associated BIS ranges may vary over time and in the context of patient status and treatment plan.

Figure 12 - BIS Range Guidelines

3.9.1 Bispectral Index (BIS)

Range = 0 – 100

The Bispectral Index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. BIS was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain. BIS is displayed as a number in the upper left corner of the screen and is plotted over time on the BIS Trend Graph. When signal quality is too low to accurately calculate a BIS value, the BIS number is not displayed.

3.9.2 System Self-Checks

The BIS VIEW monitor has several self-checking features to ensure that the system is operating properly. These include:

System Check
Initiated when the unit is started up, this test makes certain that system software and hardware components are functioning properly.

Equipment and Connection Checks
The system checks continuously to be sure that the BISx, the PIC, and patient sensors are operating properly and have not become disconnected.

DSC Self Test (Data Acquisition Test)
The DSC Self Test tests the digital signal acquisition and conversion functions of the BISx. It is a thorough test of the signal processing chain inside the BISx. It does not test the PIC or sensor. The DSC Self Test may be initiated in the Advanced Diagnostics Menu (see Section 6).

Sensor Integrity Check
This test begins each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use. Information on the current sensor can be viewed in the "System Configuration" Screen.

Impedance Check (Sensor Check)
Electrode impedance is tested when the BISx and PIC are connected and is monitored continuously unless the user has turned impedance checking off in the menu system.

Caution:
Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment, e.g., evoked potential monitors.

Ground Check
A test is performed immediately after every sensor check and at 10-minute intervals during monitoring to check the status of the patient ground connection. During the test, the EEG display shows a flat line and the message "GROUND CHECK" displays on the screen

Diagnostics
The BIS VIEW monitor provides diagnostic codes to assist the user in tracing the source of any problems that may occur. Codes are displayed in the Message Region only if the user has requested them in the Diagnostic Menu.

3.9.3 Data Memory

The monitor stores recorded trend data with time and date of acquisition. The duration of trend data stored is approximately 72 hours.

When the memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the battery has been discharged and remains when the monitor is in the power off condition.

3.9.4 Battery Operation

In the event of a power failure or interruption of power during a procedure, the monitor automatically switches to back-up battery operation. A fully charged battery will provide approximately 45 minutes of operation. When the system is running on battery, a battery icon displays above the BIS number, indicating the battery status. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color from green to orange. In addition, a "Battery Voltage Low" message blinks continuously in the Message area of the screen.

Battery recharge time is approximately 6 hours. The battery charges continually as long as the unit is plugged into A/C power.

Caution:

To completely remove power from the unit: put the monitor in Standby mode, disconnect power cord from the power cord receptacle of the monitor, then remove the battery from the monitor.

SECTION 4

4 QUICK REFERENCE GUIDE

This "Quick Reference Guide" is intended only as an operating checklist for users already familiar with the BIS VIEW monitor. Do not proceed unless you have read the "Important Safety Precautions" (Section 1 of this manual).

BASIC OPERATION

If the BIS VIEW system has already been set up, but has been put into Standby mode (after a previous surgery, for example), proceed as follows:

1. Verify that all power and other cables are connected properly.

   - The BISx's long cable to the BISx port on the monitor.
   - The Patient Interface Cable to the BISx unit.

2. Press the button in the right corner of the monitor to turn the monitor and BISx on. The button light will turn from yellow to green. The system will initiate a self-test to ensure that all equipment is operating properly.

3. Prepare sensor site and place BIS sensor on the patient in accordance with manufacturer's instructions.

4. Using the attachment clip, secure the BISx to a convenient location near the patient's head.

5. Insert the BIS sensor tab into the PIC connector until fully engaged.

You are now ready to begin monitoring. For detailed operating instructions and software configuration, read Sections 2 and 3. Current settings may be viewed at any time by viewing the appropriate menu.

SECTION 5

5 PREVENTIVE MAINTENANCE, CARE AND CLEANING

INTRODUCTION

This section describes:

- Care and cleaning procedures
- Routine maintenance
- Technical documentation
- Instrument Identification.

5.1 Care and Cleaning

WARNING:
UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

Cleaning the Monitor and BISx
Clean any spillage of blood or solutions on either the monitor or BISx as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISx performance.

Disinfecting the Monitor and BISx
Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol® Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes).

After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the BISx and PIC connector ends with alcohol and allow to dry completely.

WARNING:
WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE.

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA) AS HAZARDOUS GASES MAY RESULT.

Caution:
Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

Cleaning the Monitor Display
Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

5.2 Maintenance

The BIS VIEW monitor is designed so that no periodic adjustment or calibration is required. Suggested routine maintenance includes: periodic checking of cable integrity, system checkout, checking the battery, and checking leakage current. Instructions on replacing the battery and power supply are included in this section should replacement be necessary.

Caution:
Service or repairs must be performed only by qualified biomedical technicians.

5.2.1 Checking Cable Integrity

The BIS VIEW System should be inspected periodically to ensure that all cables are in working order, with no cuts in electrical insulation. Cables can be flexed during the system checkout (See Section 5.2.2) to ensure there are no loose wires.

5.2.2 System Checkout

A system checkout should be done periodically to verify that all system components are in working order. Follow the instructions below for System Checkout.

1. Disconnect the BISx from the monitor.

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.
   - Verify that the light to the right of the ON/Standby button is yellow.

3. Start up monitor by pressing the ON/Standby button (lower right corner).
   - Verify that the light to the right of the ON/Standby button is green.
   - Verify all self-tests complete successfully. (Do not connect or disconnect equipment, or press keys until the monitor has completed its tests.)
   - Verify next screen says "Connect BISx."

4. Connect BISx with PIC to monitor.
   - Verify that screen says "Connect sensor or cable."
5. Connect PIC and sensor.

- Verify SENSOR CHECK begins.

6. Disconnect power cord from monitor.
   - Verify 'OPERATING ON BATTERY BACKUP' is displayed.
   - Verify battery icon displays.

7. Reconnect power cord.
   - Verify battery icon is not displayed.
   - Verify 'OPERATING ON BATTERY BACKUP is not displayed.

8. End of checkout.

5.2.3 Checking the Battery

Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charging the battery for at least 6 hours. If the monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

WARNING:
ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

LEAKAGE CURRENT MUST BE CHECKED WHENEVER INSTRUMENT CASE IS OPENED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN.

Caution:
Check the battery periodically by operating a BIS VIEW monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the BIS VIEW monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VIEW monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

Note: The BIS VIEW may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. Refer to Section6.4 "Using the Reset Button."

5.2.4 Replacing the Battery

To replace the battery, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the monitor.
2. Lay monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. Note the position of the battery cable.
4. Squeeze the battery connector latch to disengage it from the back of the monitor and remove the old battery.
5. Lay the new battery in the recess with the wires at the top, and plug in the connector.
6. Replace the cover and four screws (hand-tighten only) and reconnect the A/C power cord.

5.2.5 Replacing the Power Supply

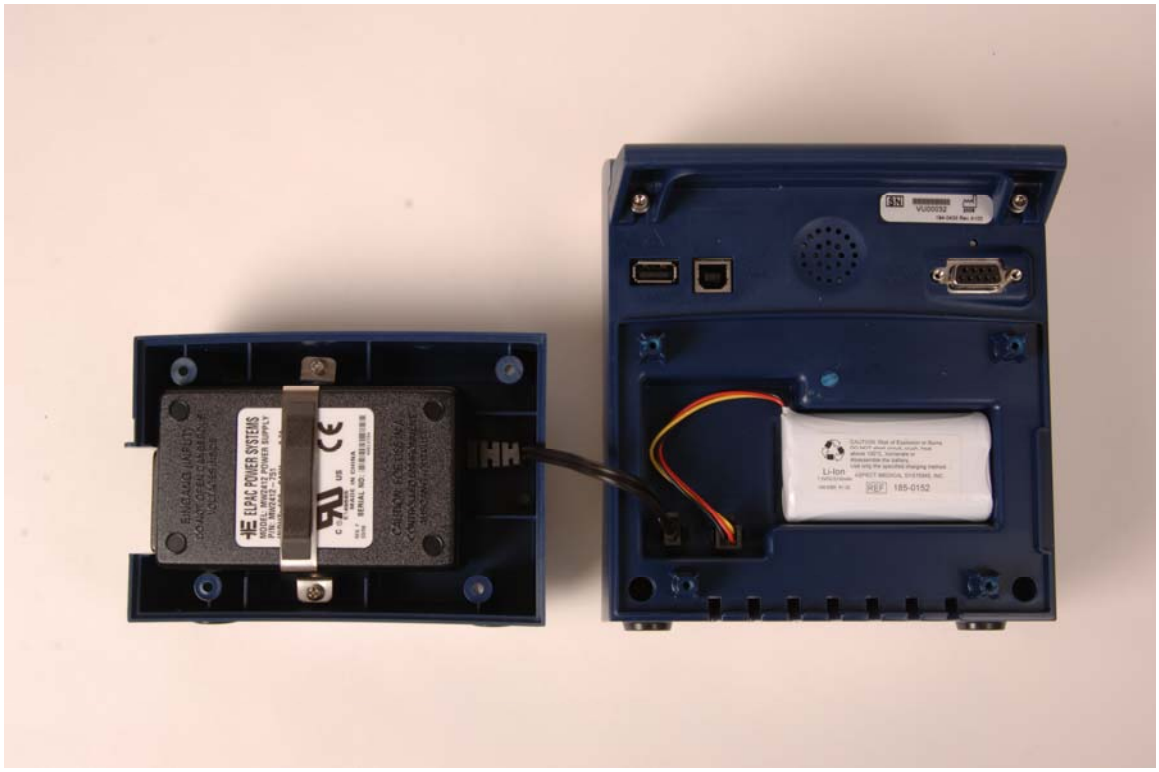


Figure 13 - Replacing the Power Supply

WARNING:
POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VIEW POWER SUPPLY.

To replace the power supply, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the BIS VIEW monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the battery and the power supply connectors.
5. Remove screws from the power supply bracket and remove the old power supply.
6. Insert new power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
7. Reconnect the power supply.
8. Reconnect the battery.
9. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

5.2.6 Checking Leakage Current

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each BIS VIEW monitor is carefully checked at the factory to verify that leakage current meets the UL60601-1 and IEC60601-1-1 safety standards.

The BIS VIEW monitor should be checked routinely for leakage current at least once a year.
Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and after every time the monitor case has been opened.

Keep in mind that liquids such as saline and Ringer's as well as blood are all excellent conductors of electricity. Avoid touching any part of the system with wet hands. Always work with clean, dry hands.

WARNING:
ELECTRICAL SHOCK HAZARD: THE MANUFACTURER'S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS. WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST LEAKAGE CURRENT BEFORE FURTHER USE.

The BIS VIEW Monitoring unit **does not** contain a ***Protective Earth Stud (GND Stud)***. Since the exposed metal parts on the rear of the BIS VIEW Monitor (Communication serial port and USB ports) are separated from live parts by double insulation, a ground continuity test does not apply to these parts. The components of the BIS VIEW Monitor that are connected to protective earth are contained within its enclosure and are not accessible to the

user of the equipment. However, as stated in the operating manual, an enclosure leakage current test should be performed on the exposed metal parts, and should be checked periodically to ensure that the integrity of the equipment's insulation system is maintained. The leakage current test should include measurement of ground wire leakage, enclosure leakage, and patient leakage.

Ground wire leakage typically can be performed automatically by connecting the A/C power cord of the BIS VIEW Monitor into a safety tester. The enclosure leakage may be measured by any safety test equipment that is capable of connecting to isolated conductive parts and measuring the current from those parts to earth. The patient connection terminals of many safety testers can be used for this purpose. The patient leakage current can be measured by connecting the patient connection terminals of a safety tester to the patient input connection (the PIC) of the BISx.

The BIS VIEW Monitor has been certified by Underwriters Laboratories to comply with IEC60601-1, as indicated on the labeling on the rear of the monitor.

5.3 Technical Documentation

The BIS VIEW Monitoring System is designed and manufactured using state-of-the-art components and manufacturing processes. Field repair or customer repairs are therefore limited by design to replacement of major component assemblies such as: the Patient Interface Cable (PIC), BISx, the BIS VIEW Monitor itself, the battery, power supply and pole clamp. Periodic software updates are possible via the USB-A port.

This BIS VIEW Operating Manual contains the maintenance and diagnostic troubleshooting information necessary for customer qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal components of the BIS VIEW monitor or the BISx.

5.4 Instrument Identification

BIS VIEW Monitor
Monitor identification information is permanently marked on the rear panel. This information includes instrument model and serial numbers, patent numbers, power ratings, cautions, and the Aspect Medical Systems' shipping address.

BISx
The BISx identification information is permanently marked on the rear panel of the BISx. The information includes instrument model and serial numbers, patent numbers, cautions, and the Aspect Medical Systems' shipping address.

Software Revision Numbers
To view the software revision numbers and other system information, go to: MENU>Diagnostics> System Configuration. See Section 6.2.3 "System Configuration Information" for instructions.

SECTION 6

6 DIAGNOSTICS AND TROUBLESHOOTING

INTRODUCTION

This section discusses:

- The Maintenance Menu
- The Diagnostic Menu
- BIS VIEW monitor messages and appropriate operator actions
- Resetting the system
- What to do if the BIS VIEW system requires service

6.1 Maintenance

The maintenance menu contains three options:

- Software Update – to update the monitor and BISx software
- Default Settings – to return the monitor to the original factory default values
- Language – to set the language that is displayed on the screens

To display the Maintenance Menu:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**. Press **[SELECT]**. The Maintenance Menu appears.

6.1.1 Software Update

The BIS VIEW system software may be updated by attaching a removable drive containing the update to the USB port on the rear of the monitor. The progress of the update displays on the monitor screen. When the update is complete, the user is asked to reset the system.

Notes:

The monitor must be connected to A/C power to perform the update.

When software is updated, all monitor configuration settings will be lost. Additionally, previously recorded data may be lost. Therefore, configuration settings and previous data should be recorded before the software update is performed.

Follow these steps to perform the update:

Caution:

Do not disconnect the BISx during the software update.

1. Before attempting an update, be sure to record your institution's saved settings, as they may be erased during the update procedure. See Section 3.6.3.5 "Settings: Active and Saved Monitor Settings" for instructions.
2. Insert the USB drive containing the software update into the USB port (Type A) at the rear of the monitor.
3. Press **[MENU]** to access the Main Menu.
4. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**, then press **[SELECT]**. The Maintenance Menu displays.
5. Press **[Software Update]**. As soon as the updating device is detected, the message "Updates Detected" appears on the screen.
6. Press **[Continue]** to initiate the update. (To skip the update, Press **[Cancel]**. The monitor will operate with the current software.) The update begins. Do NOT remove the USB drive during the updating process.
7. If the message, "Connect BISx to monitor" appears on the screen, a BISx software update is available. Connect the BISx to continue with the update, or press **[Cancel]** to skip the update.
8. When the update is complete, the message "Update Complete" appears. Press **[RESET]**. The monitor and BISx will reset, and you can then resume normal operation.

6.1.2 Default Settings

This option resets all settings to the factory default values.

To restore the original factory default settings:

1. Press **[MENU]** to access the Main Menu.
2. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**. Press **[SELECT]**. The Maintenance Menu appears.
3. Highlight **[Default Settings]**. Press **[SELECT]**. The factory default settings display on the screen.
4. Press **[RESTORE]**. The factory values become the monitor's active settings.
5. Press **[SETTINGS]** to go to the Monitor Settings screen.
6. Press **[SAVE ACTIVE]** to save the factory settings to the Saved Settings list.
7. Press **[HOME]** to exit.

For more information on Active and Saved Settings, see Section 3.6.3.5 "Settings: Active and Saved Monitor Settings."

6.1.3 Language

The BIS VIEW monitor is designed to support multiple languages, including: English, French, German, Italian, Spanish, Portuguese, Swedish and Dutch. If the screen does not display the desired language, follow these steps:

To change the language:

1. Press **[MENU]** to access the Main Menu. (The MENU key is the soft key on the far right.)
2. Use the **[▲]** or **[▼]** key to highlight **[Maintenance]**. (**Maintenance** is the fourth selection on the list). Press **[SELECT]**. The Maintenance Menu appears.

3. Highlight **[Language]**. (**Language** is the third selection on the list.) Press **[SELECT]**. The Language Menu appears.
4. Use the **[-]** or **[+]** key to scroll through the available languages until the desired language displays. Press **[SELECT]**.

To permanently save this change, go to MENU>Setup>Settings and press **[SAVE ACTIVE]**. See instructions in Section 2.6.3 "Save Settings."

6.2 Diagnostics

The Diagnostics Menu contains functions to test and maintain the BIS VIEW system. If you should experience a problem with the BIS VIEW system, Aspect's Technical Service Department will direct you in using these functions. To contact Aspect, please refer to the back cover of this manual.

The Diagnostics Menu options are:

- Impedance Checking (ON or OFF)
- Diagnostic Codes (ON or OFF)
- System Configuration Information
- Advanced Diagnostics

6.2.1 Impedance Checking

The BIS VIEW system continually checks impedance levels during a procedure by generating a 128 Hz test signal. Occasionally this signal may interfere with other equipment. If this becomes a problem, you may turn off the continuous impedance checking. Impedance levels will still be tested at startup, but once they pass, they will not be tested again until a new case is begun. (Note that you may test them at any time by pressing the "Sensor Check" touch key.)

To turn the **Impedance Checking** OFF:

1. Press **[MENU]**. The Main Menu displays.
2. Use the **[▲]** or **[▼]** key to highlight **[Diagnostics]**. Press **[SELECT]**. The Diagnostics Menu displays.
3. Highlight **[Impedance Checking]**. Press **[SELECT]**.
4. Highlight **[OFF]**. Press **[SELECT]**.

Note:

Turning off continuous impedance checking will not be saved by the "Save Settings" feature. The next time the monitor is started up or a new sensor is connected, the monitor will re-enable continuous impedance checking.

6.2.2 Diagnostic Codes

If you are experiencing problems with the BIS VIEW system, Aspect's Technical Service may direct you to turn the Diagnostic Codes ON so that numeric diagnostic values will be displayed in the Message Region of the screen.

To turn ON the Diagnostics Codes:

1. Press **[MENU]**. The Main Menu displays.
2. Use the **[▲]** or **[▼]** key to highlight **[Diagnostics]**. Press **[SELECT]**. The Diagnostics Menu displays.
3. Highlight **[Diagnostic Codes]**. Press **[SELECT]**.
4. Highlight **[On]**. Press **[SELECT]**.
5. Press **[HOME]** to exit.

6.2.3 System Configuration Information

This selection allows the user to view the current configuration of the system, including the monitor, BISx, and sensor. It also shows the revision of each language installed in the monitor.

To view System Configuration Information:

1. Press **[MENU]**. The Main Menu displays.
2. Use the **[▲]** or **[▼]** key to highlight **[Diagnostics]**. Press **[SELECT]**. The Diagnostics Menu displays.
3. Highlight **[System Configuration]**. Press **[SELECT]**.
4. Use the **[MORE]** key to view the next screen, or the **[HOME]** key to exit.

6.2.4 Advanced Diagnostics

The Advanced Diagnostics Menu contains system information and test procedures for the monitor and the BISx. Contact Aspect Medical Systems, Inc. Technical Service Department for assistance on using these functions. Contact information is located on the back page of this manual.

6.3 BIS VIEW System Messages and Corrective Actions

When an alarm is triggered, a message appears in the Message Region of the screen. Possible messages and the recommended operator actions are listed below. It is a good idea to write down the exact status message number when it occurs and have that information available if you should need service. See Section 6.5 "What to do if the BIS VIEW Monitoring System Requires Service."

BIS VIEW Messages and Operator Actions

Status Messages:	Causes:	Corrective Actions:
None (screen is blank)	Monitor has not completed its power ON diagnostics tests.	1. Monitor may take up to three minutes to initialize trend memory. Do not disconnect equipment or press keys during this time. 2. If several minutes have passed, restart monitor. 3. Reset monitor. 4. Replace monitor.
Connect BISx	1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor.	1. Connect BISx. Verify all cable connections. 2. Inspect/repair cable at connector end. 3. Replace the BISx. 4. Replace monitor.
Re-prep Sensor [0013]	1. Incorrect sensor application. 2. Poor sensor connections. 3. Sensor Check fails 4. Defective PIC. 5. Defective BISx.	1. Read Instructions on sensor package and re-prep sensor. 2. Check sensor connections. 3. Re-prep again or replace sensor. Verify Sensor Check passes. 4. Replace the PIC. 5. Replace BISx.

Status Messages:	Causes:	Corrective Actions:
Sensor Disconnected [0014]	1. Disconnected sensor. 2. Poor or contaminated connection between sensor and PIC. 3. Disconnected PIC. 4. Defective PIC. 5. Defective BISx.	1. Connect the sensor. 2. Connect/clean connection between sensor and PIC. 3. Connect the PIC. 4. Replace the PIC. 5. Replace the BISx.
Last Sensor Check Failed [0016]	1. At least one element of sensor has too high impedance, and EXIT pressed (before sensor check completes). 2. Incorrect sensor application. 3. Poor sensor connection. 4. Defective PIC. 5. Defective BISx.	1. Verify Sensor Check passes. 2. Read Instructions on sensor package and re-apply sensor. 3. Check sensor connection. 4. Replace the PIC. 5. Replace the BISx.
Unrecoverable BISx Error [0024]	1. Poor connection between BISx monitor cable and monitor. 2. Defective BISx. 3. Defective monitor.	1. Unplug BISx from monitor and plug in again. If necessary, unplug power cord and plug in again to re-start monitor. 2. Replace the BISx. 3. Replace the monitor.

Status Messages:	Causes:	Corrective Actions:
Excessive Artifact Detected in Signal [0027]	The Signal Quality is less than half of the level desirable for optimal monitoring conditions. This may occur as a result of artifact such as those generated from motion or eyeblinks. 1. Artifact, such as those generated by motion or eyeblinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note:** This message may occur as a result of artifact (non-EEG signal) such as those generated from motion (patient movement or eyeblinks) or the presence of electro-cautery, warming blankets, or other devices.	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx.

Status Messages:	Causes:	Corrective Actions:
Data unavailable due to poor signal quality [0028]	The signal quality is too low to accurately calculate a BIS value. The BIS value and other trend variables that are adversely affected by artifact are not displayed 1. Artifact, such as those generated by motion or eyeblinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note**: This message may occur as a result of artifact (non-EEG signal) such as those generated from motion (patient movement or eyeblinks) or the presence of electro-cautery, warming blankets, or other devices.	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx.
BIS Out of Target Range **Low [0029]** **High [0030]**	The BIS has fallen outside the target range set by the user.	1. Check patient. 2. Take note of BIS at limit set by user.
Isoelectric EEG Detected [0031]	No discernible EEG activity is detected for sixty-three seconds; SR=100. **Note:** This message notifies user of a flatline EEG. This is a normal condition when Sensor Simulator or Test Sensor is connected.	If unintended: 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self Test passes. 5. Verify PIC. Use Test Sensor or Sensor Simulator and Sensor Check.

Status Messages:	Causes:	Corrective Actions:
Operating On Battery Backup [0033]	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 45 minutes (when the battery is fully charged).	1. Restore the AC power. 2. Verify power cord. 3. Verify AC fuses are good. 4. Replace power supply.
Battery Voltage Low [0034]	There are only a few minutes of battery life left.	Restore AC power to avoid automatic shutdown.
Sensor Negative Ground Fault [0092] **Sensor Positive Ground Fault [0093]**	Problem is detected relating to sensor ground element.	1. Disconnect and examine sensor connection. Clean any contamination present. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.
Sensor Overcurrent [0094]	Sensor is using too much current.	1. Disconnect and examine sensor connection. Clean any contamination. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx.
No more Uses for this Sensor [0095]	Sensor has been connected and disconnected too many times.	Replace the sensor.
Sensor Invalid [0096]	1. Poor or contaminated connection between sensor and PIC. 2. An incorrect or defective sensor has been connected to the PIC. 3. Defective PIC. 4. Defective BISx.	1. Connect/clean connection between sensor and PIC. 2. Replace the sensor. 3. Replace the PIC. 4. Replace the BISx.
Unrecoverable BISx Error [1000-1999]	1. Poor connection between BISx monitor cable and monitor. 2. Defective BISx. 3. Defective monitor.	1. Unplug BISx from monitor and plug in again. If necessary, unplug power cord and plug in again to re-start monitor. 2. Replace the BISx. 3. Replace the monitor.

Status Messages:	Causes:	Corrective Actions:
Unrecoverable Monitor Error [2000-2999]	A system error has occurred. The monitor may stop operating. This can occur if the BISx is unplugged while the monitor is starting up.	1. Follow on-screen instructions (if any). 2. Turn the monitor off, then on again. 3. Reset monitor. 4. Replace monitor.
Hardware Timer Error [2902]	A system timer error has occurred.	1. Press **[Continue]** to restart monitor. 2. Turn monitor off, then on again. 3. Reset monitor. 4. Replace monitor.
Data Export Error [3000-3999]	The data export was not successful.	1. Make sure the removable drive is connected properly to the USB(A) port. 2. Check to see if drive is already full.
Software Update Error [4000-4999]	A software error has occurred.	1. Restart monitor. 2. Reset monitor. 3. Replace drive.
Trend Memory Error [5000-5999]	A memory error has occurred.	1. Restart monitor. 2. Reset monitor. 3. Replace monitor.

6.4 Using the Reset button

The Reset button is located on the back panel of the monitor. If necessary, the software can be reset by accessing this button with a ballpoint pen, paper clip or other similar tool.

6.5 What to do if the BIS VIEW Monitoring System Requires Service

Contact your local distributor to determine where servicing will occur. Aspect's Technical Service Department will assist you in isolating the problem to a specific component. Have the equipment available when you call so that you can supply the appropriate serial numbers and a detailed description of the problem. If it becomes necessary to return a unit directly to Aspect Medical Systems, follow the procedure below:

- Contact Aspect's Technical Service Department to obtain a Returned Materials Authorization (RMA) number. (The Technical Service phone number is printed on the back cover of this manual.) The RMA number must appear on the outside of the shipping container.

- Use the original shipping container, if available, or equivalent packaging to protect the product. Seal the package with plastic shipping tape rather than masking tape. Mark shipping or storage container FRAGILE.

- If the repair or replacement is covered by the warranty, Aspect will bear the costs of shipping the repaired or replacement product back to the user. All other shipping costs shall be paid by the user.

SECTION 7

7 APPENDIX I: MENUS, PROCESSED VARIABLES AND GLOSSARY

7.1 Menu Map

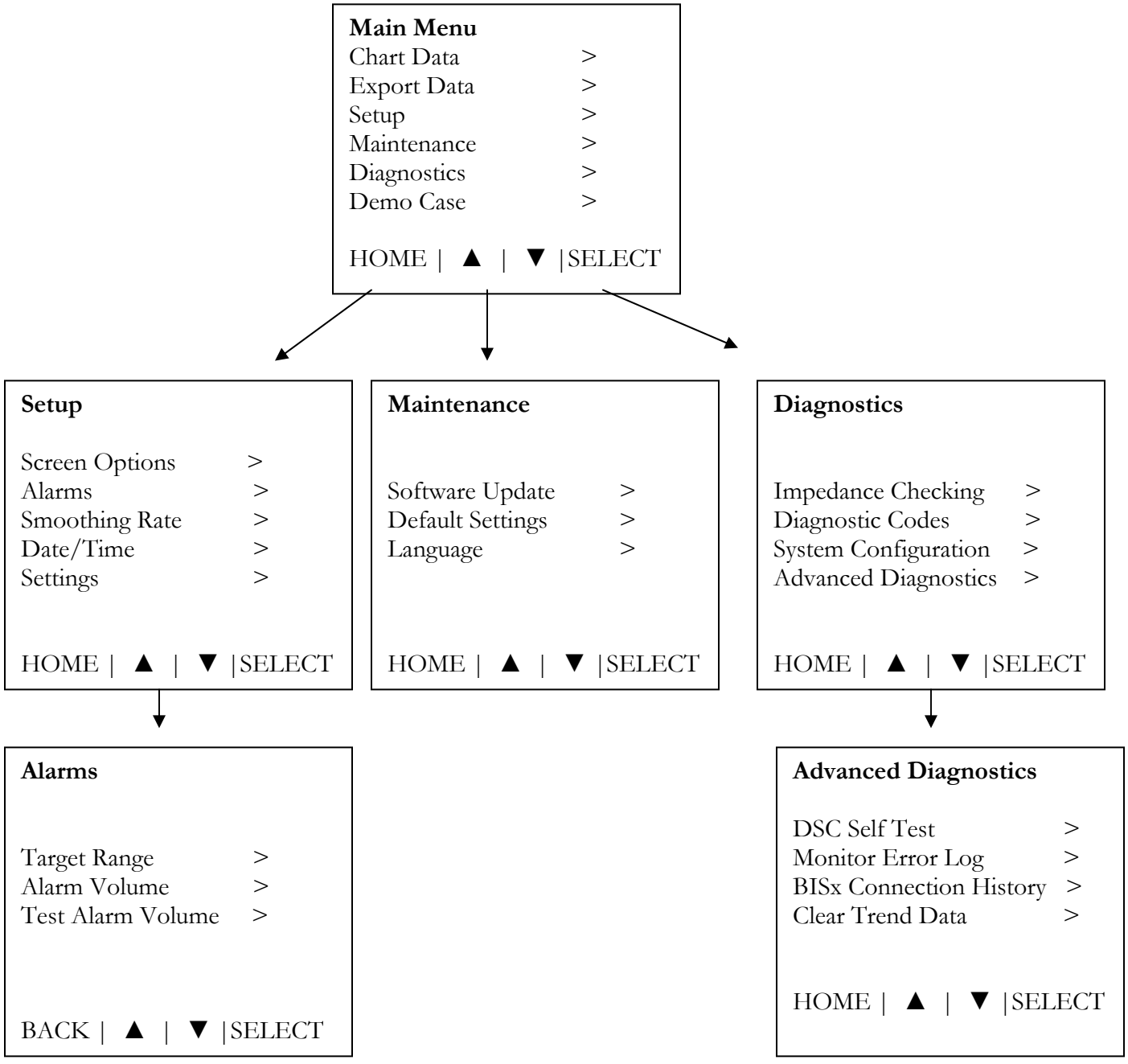


Figure 14 - BIS VIEW Menu Map

7.2 Menu Listing

Menu	Menu Item	Options *Default values appear in **Bold***
Main Menu	Chart Data Export Data Setup Maintenance Diagnostics Demo Case	1, 5, 10 or **15** minutes chart interval Run/**Stop**
Setup	Screen Options Alarms Smoothing Rate Date/Time Settings	 10, **15** or 30 seconds Save Active or Restore Saved
Screen Options	BIS Display Sensor Check Values Charting Interval Display SR Secondary Variable	**BIS Number**, Trend/Sensor Status, Trend/EEG Show or **Hide** Values 1, 5, 10 or **15** minute default chart interval On/**Off** **None**/EMG
Alarms	Target Range Alarm Volume Test Alarm Volume	 High, Medium or **Low**
Target Range	BIS High Limit BIS Low Limit Target Range Active Target Alarm	5-**100** **0**-95 Yes/**No** Off/**On**

Maintenance	Software Update Default Settings Language	 View or Restore Factory Defaults **English** French German Portuguese Spanish Dutch Italian Swedish
Diagnostics	Impedance Checking Diagnostic Codes System Configuration Advanced Diagnostics	**On**/Off On/**Off**
Advanced Diagnostics	DSC Self Test Monitor Error Log BISx Connection History Clear Trend Data	

7.3 Processed EEG Variables

Variable Name	Description	Range
Bispectral Index (BIS)	The output from a multivariate discriminate analysis that quantifies the overall bispectral properties (frequency, power, and phase) throughout the entire frequency range.	0 – 100
Signal Quality Indicator (SQI)	A measure of the signal quality for the EEG channel source(s) that is calculated based on impedance data, artifact, and other variables. Not affected by Suppression Ratio.	0 – 100 20 points per bar
EMG	The absolute power in the 70-110 Hz range. The power value is reported in dB with respect to $0.0001 \mu V^2$. All the artifact detection is turned off for this variable.	30 – 80 dB Trend 30 – 55 dB Bar Graph
Suppression Ratio (SR)	The percentage of epochs in the past 63 seconds in which the EEG signal is considered suppressed.	0 – 100 %

7.4 Glossary

Amplitude
The maximum absolute value reached by a voltage or current waveform.

Artifact
An electrical waveform with characteristics that arise from sources other than the heart or brain.

Bispectral Index
The Bispectral Index is a continuous processed EEG parameter that correlates to the patient's level of hypnosis, where 100=awake and 0=flat line EEG. BIS was designed to correlate with "hypnotic" clinical endpoints (sedation, lack of awareness, and memory) and to track changes in the effects of anesthetics on the brain.

BIS Sensor
A single patient use, disposable, pre-gelled 4 electrode array that is applied directly to the patient's forehead to record electrophysiological signals. The BIS sensor tab contains an electric smart card memory device that stores configuration and identification information.

BISx
The BISx is the small unit that attaches to the BIS VIEW monitor via its own monitor cable, and attaches to a BIS sensor via the Patient Interface Cable (PIC). It acquires and processes EEG information and sends it to the monitor for display.

Electroencephalogram (EEG)
A visual representation of the rhythmic fluctuations of electric potential between parts of the brain (brain waves).

Electromyelogram (EMG)
A visual representation of the power (in decibels) in the frequency range 70 – 110 Hz. This frequency range contains power from muscle activity as well as power from other high-frequency artifacts.

Epoch
A short interval of arbitrarily defined length.

Impedance
The measure of the quality of the sensor electrodes' contact. Impedance is the amount of resistance that the electrical current encounters. Impedance is continuously monitored to ensure adequate signal quality.

Isoelectric EEG
Electrocerebral silence (flat EEG) or no significant electrical activity in the brain. Specifically, periods >240 msecs during which the electroencephalographic voltage did not exceed 5 [mu]V). A long period (>1 minute) of isoelectric EEG leads to suppression, indicated by a high suppression ratio and the message "Isoelectric EEG."

Montage
Standardized electrode locations.

Patient Interface Cable (PIC)
The cable that connects the BIS sensor to the BISx.

Signal Quality Indicator (SQI)
A measure of the signal quality for the EEG channel source that is calculated based on impedance data, artifact, and other variables.

Smoothing Rate
The rate over which the BIS value is averaged.

Suppression Ratio (SR)
A calculated parameter that indicates when an isoelectric (flatline) condition may exist. Suppression ratio is the percentage of time over the last 63-second period that the signal is considered to be in the suppressed state (isoelectric). When SR equals 100, it means that during 100% of the last 63 second time period, no significant amount of electrical activity was detected.

SECTION 8

8 APPENDIX II: SPECIFICATIONS, WARRANTY, SOFTWARE LICENSE AGREEMENT AND PATENTS

8.1 Specifications

This section lists specifications for the BIS VIEW Monitoring System.

General Specifications:

- Product Description: BIS (Bispectral Index) monitoring system for display of processed data and real-time EEG waveforms
- Monitor Weight: 2.65 lbs (1.2 kg)
- Monitor Dimensions: 6 in wide x 6.5 in high x 5 in deep (15.2 cm x 16.5 cm x 12.7 cm)
- Display Size: 3.6 in (9.1 cm)
- Digital Output: USB ports A, B, RS232 serial port
- Power Requirements: 100-240 VAC, 50-60 Hz, 0.7 ampere max.
- Electrical Safety: Conforms to: UL 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1
- Battery Backup: 45 minutes at full operation
Recharge Time: 6 hours
- Software Updates: User-via USB port (Type A)

EEG Specifications:

- Epoch Duration: 2 seconds
- Artifact Rejection: Automatic
- Input Amplifier Range +/- 1 mV
- EEG Scales: One Channel Display: 25 μV/div (+/- 50 μV full scale)
- EEG Sweep Speed: 25 mm/sec
- Computed Parameters: Bispectral Index, EMG, SR and Signal Quality Indicator
- User-defined Displays: Trend and real-time EEG waveforms
- Update Rate: 1 second for BIS number, 10 seconds for Trend
- Alarms: Auditory and visual, user adjustable limits
- Filters: 2 – 70 Hz with notch

BISx Specifications:

- BISx:
  - Weight: 10.0 oz (0.284 kg) including integral cable
  - Dimensions: 3.75 in diameter x 2.5 in thick (9.5 cm x 6.3 cm)
  - Cable Length: 9 ft (2.7 m) Integral BISx Cable; 4 ½ ft (1.4 m) from BISx to sensor connector
- Analog to Digital Converter: Noise-shaped sigma-delta
- Sampling Rate: 16,384 samples/second
- Resolution: 16 Bits at 256 samples/second
- Input Impedance: 50 Mohms typical
- Noise: < 0.3 μV RMS (2.0 μV peak-to-peak); 0.25 Hz to 50 Hz
- Common Mode Rejection: (Isolation mode) 110 dB at 50/60 Hz to earth ground
- Frequency/Bandwidth: 0.16 – 450 Hz

Type of Protection against Electric Shock of the System:

Class 1: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Degree of Protection against Electric Shock of the System:

Type BF: Equipment providing a degree of protection against electric shock regarding allowable leakage currents and reliability of the protective earth ground connection with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. The circuitry inside the BIS VIEW monitor is isolated from the mains in accordance with IEC60601-1. Patient isolation is accomplished within the BISx.

Degree of Protection against effects of Cardiac Defibrillation:

The BIS VIEW system provides protection for the operator and patient during cardiac defibrillation. This protection is achieved via the isolation barrier within the BISx.

Degree of Protection against the Ingress of Water:

Monitor degree of protection rating: IPX2 (ingress of water vertically dripping).
BISx degree of protection rating: IPX4 (splash proof).

Mode of Operation of the System:

Continuous: Operation under normal load for a normal period without exceeding the specified limits of temperature.

Classification:

MEDICAL ELECTRONIC EQUIPMENT

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.® WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1.

8.2 Electromagnetic Compatibility Specifications

The BIS VIEW Monitoring System requires special precautions regarding Electromagnetic Compatibility (EMC). The BIS VIEW system must be set up and put into service according to the EMC guidance information provided in this section.

Portable and mobile radio frequency communications equipment can affect the operation of the BIS VIEW Monitoring System. Refer to the EMC guidance information and Cautions provided in this manual.

8.2.1 Accessories

The BIS VIEW Monitoring System complies with the requirements of IEC 60601-1-2:2001 when used with the accessories listed in Section 2 of the Operating Manual. In addition, the BIS VIEW system must be used only with the power cord provided.

When using a removable drive to load new versions of software into the BIS VIEW monitor, no cables or other accessories should be connected to the device. The BIS VIEW monitor should be connected to the mains through the appropriate power cord, and the removable drive should be plugged into the USB-A connector on the back of the monitor.

Caution:

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VIEW Monitoring System.

8.2.2 IEC 60601-1-2:2001 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for the BIS VIEW Monitoring System as per IEC 60601-1-2.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The BIS VIEW system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The BIS VIEW system is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Caution:

The BIS VIEW system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VIEW Monitor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VIEW system is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines.	±2 kV for power supply lines. ±1 kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical hospital environment. If the user of the BIS VIEW system requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the BIS VIEW Monitor be powered by an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
NOTE: UT is the AC mains voltage prior to the application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VIEW system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the BIS VIEW system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	d = $1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	d = $1.2\sqrt{P}$, 80 MHz to 800 MHz d = $2.3\sqrt{P}$, 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIS VIEW system is used exceeds the applicable RF compliance level above, the BIS VIEW system should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the BIS VIEW system
[b] Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BIS VIEW Monitor

The BIS VIEW Monitoring System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BIS VIEW system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIS VIEW system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

8.3 Warranty

Aspect warrants to the initial Purchaser that the BIS VIEW monitor and the BISx ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Aspect's obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Aspect reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Aspect directly (see contact information on the back cover of this manual). Aspect will authorize Purchaser to return the Warranted Product (or part thereof) to Aspect. Aspect shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Aspect's property. In the course of warranty service, Aspect may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Aspect reasonably determines that a repair or replacement is covered by the warranty, Aspect shall bear the costs of shipping the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a Product to Aspect in unsuitable packaging, any physical damage present in the Product on receipt by Aspect (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

This warranty does not extend to any Warranted Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Aspect's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than Aspect; or that have been disassembled, serviced, or reassembled by anyone other than Aspect, unless authorized by Aspect. Aspect shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Aspect makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Aspect or an Aspect-authorized distributor or (c) with respect to any product sold under a brand name other than Aspect Medical Systems, Inc.

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8.5 List of Patents

(US) 4,907,597
(US) 5,010,891 • (Europe) 0,468,999 • (Australia) 638,708 • (Canada) 2,051,683 • (Japan) 3,136,408)
(US) 5,320,109 • (Europe) 0,610,365; 0,898,234 • Canada 2,122,032; 2,434,275
(Europe) 0,665,728
(US) 5,381,804 • (Europe) 0,738,496 • (Canada) 2,146,979
(US) 5,458,117 • (Europe) 0,764,001 • (Canada) 2,191,594
(US) 5,792,069 • (Europe) 0,957,761 • (Australia) 732,539 • (Canada) 2,275,901
(US) 6,298,255 • (Europe) 1,182,965 • (Australia) 780,076 • (Mexico) 233,167
(US) 6,882,166
(US) 6,985,833
(US) 7,161,362

European patents may include those in each of the following countries; Austria, Belgium, France, Germany, Spain, Switzerland and the United Kingdom

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Contact Information for:

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA 02062
U.S.A.

Main Business Phone: (617) 559-7000
Main Business Fax: (617) 559-7400
Customer Service: (888) BIS-INDE(X)…press (6), or
(800) 442-7688 … press (6)
Technical Service: (800) 442-2051

Email: bis_info@aspectms.com
Web: www.aspectmedical.com

EC REP

Aspect Medical Systems International B.V.
Rijnzathe 7d2
3454 PV De Meern
The Netherlands

Main Business Phone: +31.30.662.9140
Main Business Fax: +31.30.662.9150
Email: amsint@aspectms.com

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